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Exhibit 668

21 USC 823

- United States Code
  - TITLE 21 - FOOD AND DRUGS
    - CHAPTER 13 - DRUG ABUSE PREVENTION AND CONTROL
      - SUBCHAPTER I - CONTROL AND ENFORCEMENT
        - PART C - REGISTRATION OF MANUFACTURERS, DISTRIBUTORS DISPENSERS OF CONTROLLED SUBSTANCES

U.S. Code as of: 01/06/03

Section 823. Registration requirements

Related Res

Health Law

Department of J Human Ser Directo

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Agriculture D

(a) Manufacturers of controlled substances in schedule I or II

The Attorney General shall register an applicant to manufacture controlled substances in schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

(b) Distributors of controlled substances in schedule I or II

The Attorney General shall register an applicant to distribute a controlled substance in schedule I or II unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent

with the public health and safety.

(c) Limits of authorized activities

Registration granted under subsections (a) and (b) of this section shall not entitle a registrant to (1) manufacture or distribute controlled substances in schedule I or II other than those specified in the registration, or (2) manufacture any quantity of those controlled substances in excess of the quota assigned pursuant to section 826 of this title.

(d) Manufacturers of controlled substances in schedule III, IV, or V

The Attorney General shall register an applicant to manufacture controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule III, IV, or V compounded therefrom into other than legitimate medical, scientific, or industrial channels;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture, distribution, and dispensing of controlled substances, and the existence in the establishment of effective controls against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

(e) Distributors of controlled substances in schedule III, IV, or V

The Attorney General shall register an applicant to distribute controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

(f) Research by practitioners; pharmacies; research applications; construction of Article 7 of the Convention on Psychotropic Substances

The Attorney General shall register practitioners (including pharmacies, as distinguished from pharmacists) to dispense, or conduct research with, controlled substances in schedule II, III, IV, or V, if the applicant is authorized to dispense, or conduct research with respect to, controlled substances under the laws of the State in which he practices. The Attorney General may deny an application for such registration if he determines that the issuance of such registration would be inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting

research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

Separate registration under this part for practitioners engaging in research with controlled substances in schedule II, III, IV, or V, who are already registered under this part in another capacity, shall not be required. Registration applications by practitioners wishing to conduct research with controlled substances in schedule I shall be referred to the Secretary, who shall determine the qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol. The Secretary, in determining the merits of each research protocol, shall consult with the Attorney General as to effective procedures to adequately safeguard against diversion of such controlled substances from legitimate medical or scientific use. Registration for the purpose of bona fide research with controlled substances in schedule I by a practitioner deemed qualified by the Secretary may be denied by the Attorney General only on a ground specified in section 824(a) of this title. Article 7 of the Convention on Psychotropic Substances shall not be construed to prohibit, or impose additional restrictions upon, research involving drugs or other substances scheduled under the convention which is conducted in conformity with this subsection and other applicable provisions of this subchapter.

(g) Practitioners dispensing narcotic drugs for narcotic treatment; annual registration; separate registration; qualifications; waiver

(1) Except as provided in paragraph (2), practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment shall obtain annually a separate registration for that purpose. The Attorney General shall register an applicant to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment (or both)

(A) if the applicant is a practitioner who is determined by the Secretary to be qualified (under standards established by the Secretary) to engage in the treatment with respect to which registration is sought;

(B) if the Attorney General determines that the applicant will comply with standards established by the Attorney General respecting (i) security of stocks of narcotic drugs for such treatment, and (ii) the maintenance of records (in accordance with section 827 of this title) on such drugs; and

(C) if the Secretary determines that the applicant will comply with standards established by the Secretary (after consultation with the Attorney General) respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment.

(2)(A) Subject to subparagraphs (D) and (J), the requirements of paragraph (1) are waived in the case of the dispensing (including the prescribing), by a practitioner, of narcotic drugs in schedule III, IV, or V or combinations of such drugs if the practitioner meets the conditions specified in subparagraph (B) and the narcotic drugs or combinations of such drugs meet the conditions specified in subparagraph (C).

(B) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to a practitioner are that, before the initial dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or

detoxification treatment, the practitioner submit to the Secretary a notification of the intent of the practitioner to begin dispensing the drugs or combinations for such purpose, and that the notification contain the following certifications by the practitioner:

(i) The practitioner is a qualifying physician (as defined in subparagraph (G)).

(ii) With respect to patients to whom the practitioner will provide such drugs or combinations of drugs, the practitioner has the capacity to refer the patients for appropriate counseling and other appropriate ancillary services.

(iii) In any case in which the practitioner is not in a group practice, the total number of such patients of the practitioner at any one time will not exceed the applicable number. For purposes of this clause, the applicable number is 30, except that the Secretary may by regulation change such total number.

(iv) In any case in which the practitioner is in a group practice, the total number of such patients of the group practice at any one time will not exceed the applicable number. For purposes of this clause, the applicable number is 30, except that the Secretary may by regulation change such total number, and the Secretary for such purposes may by regulation establish different categories on the basis of the number of practitioners in a group practice and establish for the various categories different numerical limitations on the number of such patients that the group practice may have.

(C) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to narcotic drugs in schedule III, IV, or V or combinations of such drugs are as follows:

(i) The drugs or combinations of drugs have, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or section 262 of title 42, been approved for use in maintenance or detoxification treatment.

(ii) The drugs or combinations of drugs have not been the subject of an adverse determination. For purposes of this clause, an adverse determination is a determination published in the Federal Register and made by the Secretary, after consultation with the Attorney General, that the use of the drugs or combinations of drugs for maintenance or detoxification treatment requires additional standards respecting the qualifications of practitioners to provide such treatment, or requires standards respecting the quantities of the drugs that may be provided for unsupervised use.

(D)(i) A waiver under subparagraph (A) with respect to a practitioner is not in effect unless (in addition to conditions under subparagraphs (B) and (C)) the following conditions are met:

(I) The notification under subparagraph (B) is in writing and states the name of the practitioner.

(II) The notification identifies the registration issued for the practitioner pursuant to subsection (f) of this section.

(III) If the practitioner is a member of a group practice, the notification states the names of the other practitioners in the practice and identifies the registrations issued for the other practitioners pursuant to subsection (f) of this section.

(ii) Upon receiving a notification under subparagraph (B), the Attorney General shall assign the practitioner involved an identification number under this paragraph for inclusion with the registration issued for the practitioner pursuant to subsection (f) of this section. The identification number so assigned shall be appropriate to preserve the confidentiality of patients for whom the practitioner has dispensed narcotic drugs under a waiver under subparagraph (A).

(iii) Not later than 45 days after the date on which the

Secretary receives a notification under subparagraph (B), the Secretary shall make a determination of whether the practitioner involved meets all requirements for a waiver under subparagraph (B). If the Secretary fails to make such determination by the end of the such 45-day period, the Attorney General shall assign the physician an identification number described in clause (ii) at the end of such period.

(E)(i) If a practitioner is not registered under paragraph (1) and, in violation of the conditions specified in subparagraphs (B) through (D), dispenses narcotic drugs in schedule III, IV, or V or combinations of such drugs for maintenance treatment or detoxification treatment, the Attorney General may, for purposes of section 824(a)(4) of this title, consider the practitioner to have committed an act that renders the registration of the practitioner pursuant to subsection (f) of this section to be inconsistent with the public interest.

(ii)(I) Upon the expiration of 45 days from the date on which the Secretary receives a notification under subparagraph (B), a practitioner who in good faith submits a notification under subparagraph (B) and reasonably believes that the conditions specified in subparagraphs (B) through (D) have been met shall, in dispensing narcotic drugs in schedule III, IV, or V or combinations of such drugs for maintenance treatment or detoxification treatment, be considered to have a waiver under subparagraph (A) until notified otherwise by the Secretary, except that such a practitioner may commence to prescribe or dispense such narcotic drugs for such purposes prior to the expiration of such 45-day period if it facilitates the treatment of an individual patient and both the Secretary and the Attorney General are notified by the practitioner of the intent to commence prescribing or dispensing such narcotic drugs.

(II) For purposes of subclause (I), the publication in the Federal Register of an adverse determination by the Secretary pursuant to subparagraph (C)(ii) shall (with respect to the narcotic drug or combination involved) be considered to be a notification provided by the Secretary to practitioners, effective upon the expiration of the 30-day period beginning on the date on which the adverse determination is so published.

(F)(i) With respect to the dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment, a practitioner may, in his or her discretion, dispense such drugs or combinations for such treatment under a registration under paragraph (1) or a waiver under subparagraph (A) (subject to meeting the applicable conditions).

(ii) This paragraph may not be construed as having any legal effect on the conditions for obtaining a registration under paragraph (1), including with respect to the number of patients who may be served under such a registration.

(G) For purposes of this paragraph:

(i) The term ''group practice'' has the meaning given such term in section 1395nn(h)(4) of title 42.

(ii) The term ''qualifying physician'' means a physician who is licensed under State law and who meets one or more of the following conditions:

(I) The physician holds a subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties.

(II) The physician holds an addiction certification from the American Society of Addiction Medicine.

(III) The physician holds a subspecialty board certification in addiction medicine from the American Osteopathic Association.

(IV) The physician has, with respect to the treatment and management of opiate-dependent patients, completed not less than eight hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or any other organization that the Secretary determines is appropriate for purposes of this subclause.

(V) The physician has participated as an investigator in one or more clinical trials leading to the approval of a narcotic drug in schedule III, IV, or V for maintenance or detoxification treatment, as demonstrated by a statement submitted to the Secretary by the sponsor of such approved drug.

(VI) The physician has such other training or experience as the State medical licensing board (of the State in which the physician will provide maintenance or detoxification treatment) considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients.

(VII) The physician has such other training or experience as the Secretary considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients. Any criteria of the Secretary under this subclause shall be established by regulation. Any such criteria are effective only for 3 years after the date on which the criteria are promulgated, but may be extended for such additional discrete 3-year periods as the Secretary considers appropriate for purposes of this subclause. Such an extension of criteria may only be effectuated through a statement published in the Federal Register by the Secretary during the 30-day period preceding the end of the 3-year period involved.

(H)(i) In consultation with the Administrator of the Drug Enforcement Administration, the Administrator of the Substance Abuse and Mental Health Services Administration, the Director of the National Institute on Drug Abuse, and the Commissioner of Food and Drugs, the Secretary shall issue regulations (through notice and comment rulemaking) or issue practice guidelines to address the following:

(I) Approval of additional credentialing bodies and the responsibilities of additional credentialing bodies.

(II) Additional exemptions from the requirements of this paragraph and any regulations under this paragraph.

Nothing in such regulations or practice guidelines may authorize any Federal official or employee to exercise supervision or control over the practice of medicine or the manner in which medical services are provided.

(ii) Not later than 120 days after October 17, 2000, the Secretary shall issue a treatment improvement protocol containing best practice guidelines for the treatment and maintenance of opiate-dependent patients. The Secretary shall develop the protocol in consultation with the Director of the National Institute on Drug Abuse, the Administrator of the Drug Enforcement Administration, the Commissioner of Food and Drugs, the Administrator of the Substance Abuse and Mental Health Services Administration and other substance abuse disorder professionals. The protocol shall be guided by science.

(I) During the 3-year period beginning on the date of approval by the Food and Drug Administration of a drug in schedule III, IV, or V, a State may not preclude a practitioner from dispensing or prescribing such drug, or combination of such drugs, to patients for maintenance or detoxification treatment in accordance with this

paragraph unless, before the expiration of that 3-year period, the State enacts a law prohibiting a practitioner from dispensing such drugs or combinations of drug. (FOOTNOTE 1)

(FOOTNOTE 1) So in original. Probably should be ''combinations of drugs.''.

(J)(i) This paragraph takes effect the date referred to in subparagraph (I), and remains in effect thereafter except as provided in clause (iii) (relating to a decision by the Secretary or the Attorney General that this paragraph should not remain in effect).

(ii) For purposes relating to clause (iii), the Secretary and the Attorney General may, during the 3-year period beginning on October 17, 2000, make determinations in accordance with the following:

(I) The Secretary may make a determination of whether treatments provided under waivers under subparagraph (A) have been effective forms of maintenance treatment and detoxification treatment in clinical settings; may make a determination of whether such waivers have significantly increased (relative to the beginning of such period) the availability of maintenance treatment and detoxification treatment; and may make a determination of whether such waivers have adverse consequences for the public health.

(II) The Attorney General may make a determination of the extent to which there have been violations of the numerical limitations established under subparagraph (B) for the number of individuals to whom a practitioner may provide treatment; may make a determination of whether waivers under subparagraph (A) have increased (relative to the beginning of such period) the extent to which narcotic drugs in schedule III, IV, or V or combinations of such drugs are being dispensed or possessed in violation of this chapter; and may make a determination of whether such waivers have adverse consequences for the public health.

(iii) If, before the expiration of the period specified in clause (ii), the Secretary or the Attorney General publishes in the Federal Register a decision, made on the basis of determinations under such clause, that this paragraph should not remain in effect, this paragraph ceases to be in effect 60 days after the date on which the decision is so published. The Secretary shall in making any such decision consult with the Attorney General, and shall in publishing the decision in the Federal Register include any comments received from the Attorney General for inclusion in the publication. The Attorney General shall in making any such decision consult with the Secretary, and shall in publishing the decision in the Federal Register include any comments received from the Secretary for inclusion in the publication.

(h) Applicants for distribution of list I chemicals

The Attorney General shall register an applicant to distribute a list I chemical unless the Attorney General determines that registration of the applicant is inconsistent with the public interest. Registration under this subsection shall not be required for the distribution of a drug product that is exempted under section 802(39)(A)(iv) of this title. In determining the public interest for the purposes of this subsection, the Attorney General shall consider -

(1) maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;

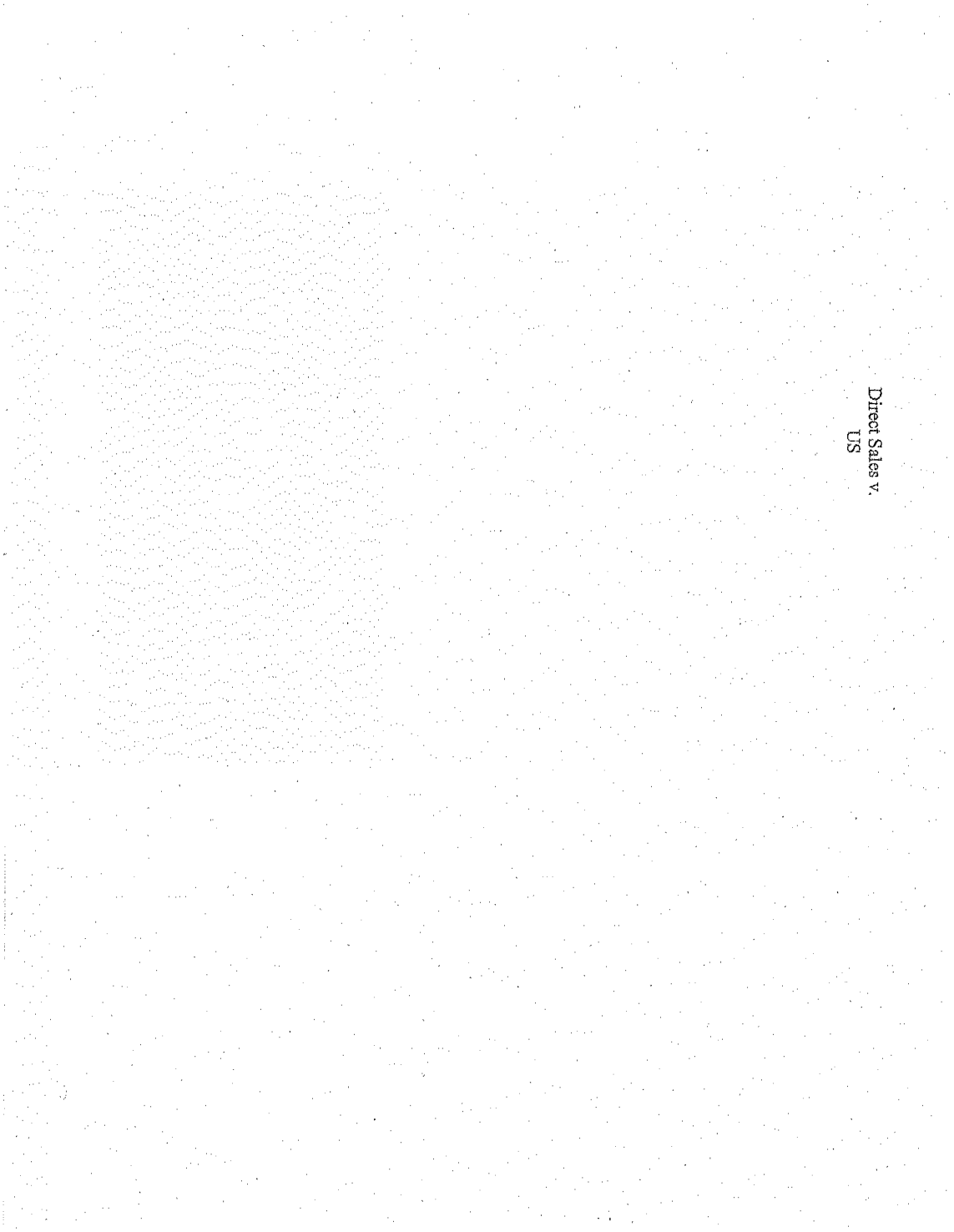
(2) compliance by the applicant with applicable Federal, State, and local law;

(3) any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;

(4) any past experience of the applicant in the manufacture and distribution of chemicals; and

(5) such other factors as are relevant to and consistent with the public health and safety.

Previous [Notes] Next


Direct Sales v.
US

U.S. Supreme Court

DIRECT SALES CO. v. UNITED STATES, 319 U.S. 703 (1943)

319 U.S. 703

DIRECT SALES CO., Inc.,
v.
UNITED STATES.
No. 593.

Argued April 12, 1943.
Decided June 14, 1943.

[319 U.S. 703, 704] Mr. Wm. B. Mahoney, of Buffalo, N.Y., for petitioner.

Mr. Valentine Brookes, of Washington, D.C., for respondent.

Mr. Justice RUTLEDGE delivered the opinion of the Court.

Petitioner, a corporation, was convicted of conspiracy to violate the Harrison Narcotic Act. 1 It challenges the sufficiency of the evidence to sustain the conviction. Because of asserted conflict with United States v. Falcone, 311 U.S. 205, 61 S.Ct. 204, certiorari was granted.

Petitioner is a registered drug manufacturer and wholesaler. 2 It conducts a nationwide mail-order business from Buffalo, New York. The evidence relates chiefly to its transactions with one Dr. John V. Tate and his dealings with others. He was a registered physician, practicing in Calhoun Falls, South Carolina, a community of about 2000 persons. He dispensed illegally vast quantities of morphine sulphate purchased by mail from petitioner. The indictment charged petitioner, Dr. Tate, and three others, Black, Johnson and Foster, to and through whom Tate illegally distributed the drugs, with conspiring to violate [319 U.S. 703, 705] Sections 1 and 2 of the Act,3 over a period extending from 1933 to 1940. Foster was granted a severance, Black and Johnson pleaded guilty, and petitioner and Dr. Tate were convicted. Direct Sales alone appealed. The Circuit Court of Appeals affirmed. 131 F.2d 835.

The parties here are at odds concerning the effect of the Falcone decision as applied to the facts proved in this case. The salient facts are that Direct Sales sold morphine sulphate to Dr. Tate in such quantities, so frequently and over so long a period it must have known he could not dispense the amounts received in lawful practice and was therefore distributing the drug illegally. Not only so, but it actively stimulated Tate's purchases.

He was a small-town physician practicing in a rural section. All of his business with Direct Sales was done by mail. Through its catalogues petitioner first made [319 U.S. 703, 706] contact with him prior to 1933. Originally he purchased a variety of pharmaceuticals. But gradually the character of his purchases narrowed, so that during the last two years of the period alleged for the conspiracy he ordered almost nothing but morphine sulphate. At all times during the period he purchased the major portion of his morphine sulphate from petitioner. The orders were made regularly on his official order forms. The testimony shows the average physician in the United States does not require more than 400 one-quarter grain tablets annually for legitimate use. Although Tate's initial purchases in 1933 were smaller, they

gradually increased until, from November, 1937, to January, 1940, they amounted to 79,000 one-half grain tablets. In the last six months of 1939, petitioner's shipments to him averaged 5,000 to 6,000 half-grain tablets a month, enough as the Government points out to enable him to give 400 average doses every day.

These quantity sales were in line with the general mail-order character of petitioner's business. By printed catalogues circulated about three times a month, it solicits orders from retail druggists and physicians located for the most part in small towns throughout the country. Of annual sales of from $300,000 to $350,000 in the period 1936 to 1940, about fifteen per cent by revenue and two-and-a-half per cent by volume were in narcotics. he mail- order plan enabled petitioner to sell at prices considerably lower than were charged by its larger competitors, who maintained sales forces and traveling representatives. By offering fifty per cent discounts on narcotics, it 'pushed' quantity sales. Instead of listing narcotics, like morphine sulphate, in quantities not exceeding 100 tablets, as did many competitors, Direct Sales for some time listed them in 500, 1000 and 5000 tablet units. By this policy it attracted customers, including a dispropor- [319 U.S. 703, 707] tionately large group of physicians who had been convicted of violating the Harrison Act.

All this was not without warning, purpose or design. In 1936 the Bureau of Narcotics informed petitioner it was being used as a source of supply by convicted physicians. 4 The same agent also warned that the average physician would order no more than 200 to 400 quarter-grain tablets annually5 and requested it to eliminate the listing of 5000 lots. It did so, but continued the 1000 and 500 lot listings at attractive discounts. It filled no more orders from Tate for more than 1000 tablets, but continued to supply him for that amount at half-grain strength. On one occasion in 1939 he ordered on one form 1000 half and 100 quarter grains. Petitioner sent him the 1000 and advised him to reorder the 100 on a separate order form. It attached to this letter a sticker printed in red suggesting anticipation of future needs and taking advantage of discounts offered. Three days later Tate ordered 1000 more tablets, which petitioner sent out. In 1940, at the Bureau's suggestion, Direct Sales eliminated its fifty and ten per cent discounts. But on doing so it translated its discount into its net price.

Tate distributed the drugs to and through addicts and purveyors, including Johnson, Black and Foster. Although he purchased from petitioner at less than two dol- [319 U.S. 703, 708] lars, he sold at prices ranging from four to eight dollars per 100 half- grain tablets and purveyors from him charged addicts as much as $25 per hundred.

On this evidence, the Government insists the case is in different posture from that presented in United States v. Falcone. It urges that the effort there was to connect the respondents with a conspiracy between the distillers on the basis of the aiding and abetting statute. 6 The attempt failed because the Court held the evidence did not establish the respondents knew of the distillers' conspiracy. There was no attempt to link the supplier and the distiller in a conspiracy inter sese. But in this case that type of problem is presented. Direct Sales was tried, and its conviction has been sustained, according to the claim, on the theory it could be convicted only if it were found that it and Tate conspired together to subvert the order form provisions of the Harrison Act. As the brief puts the Government's view, 'Petitioner's guilt was not made to depend at all upon any guilt of Dr. Tate growing out of his relationship to defendants other than petitioner or upon whether these other defendants were linked with the Tate-Direct Sales conspiracy.'

On the other hand, petitioner asserts this case falls squarely within the facts and the ruling in the Falcone case. It insists there is no more to show conspiracy between itself and Tate than there was to show conspiracy between the respondent sellers and the purchasing distillers there. At most, it urges, there were only legal sales by itself to Dr. Tate, accompanied by knowledge he was distributing goods illegally. But this, it contends, cannot amount to conspiracy on its part with him, since in the Falcone case the respondents sold to the distillers, knowing they would use the goods in illegal distillation. [319 U.S. 703, 709] Petitioner obviously misconstrues the effect of the Falcone decision in one respect. This is

in regarding it as deciding that one who sells to another with knowledge that the buyer will use the article for an illegal purpose cannot, under any circumstances, be found guilty of conspiracy with the buyer to further his illegal end. The assumption seems to be that, under the ruling, so long as the seller does not know there is a conspiracy between the buyer and others, he cannot be guilty of conspiring with the buyer, to further the latter's illegal and known intended use, by selling goods to him.

The Falcone case creates no such sweeping insulation for sellers to known illicit users. That decision comes down merely to this, that one does not become a party to a conspiracy by aiding and abetting it, through sales of supplies or otherwise, unless he knows of the conspiracy; and the inference of such knowledge cannot be drawn merely from knowledge the buyer will use the goods illegally. The Government did not contend, in those circumstances, as the opinion points out, that there was a conspiracy between the buyer and the seller alone. It conceded that on the evidence neither the act of supplying itself nor the other proof was of such a character as imported an agreement or concert of action between the buyer and the seller amounting to conspiracy. This was true, notwithstanding some of the respondents could be taken to know their customers would use the purchased goods in illegal distillation.

The scope of the concession must be measured in the light of the evidence with reference to which it was made. This related to both the volume of the sales and to casual and unexplained meetings of some of the respondents with others who were convicted as conspirators. The Court found this evidence too vague and uncertain to support a finding the respondents knew of the distillers' conspiracy, [319 U.S. 703, 710] though not inadequate in some instances to sustain one that the seller knew the buyer would use the goods for illegal distilling. It must be taken also that the Government regarded the same evidence as insufficient to show the seller conspired directly with the buyer, by selling to him with knowledge of his intended illegal use.

Whether or not it was consistent in making this concession and in regarding the same evidence as sufficient to show that the sellers knew of and joined the buyers' distilling ring is not material. Nor need it be determined whether the Government conceded too much. We do not now undertaken to say what the Court was not asked and therefore declined to say in the Falcone case, namely, that the evidence presented in that case was sufficient to sustain a finding of conspiracy between the seller and the buyer inter sese. For, regardless of that, the facts proved in this case show much more than the evidence did there.

The commodities sold there were articles of free commerce, sugar, cans, etc. They were not restricted as to sale by order form, registration, or other requirements. When they left the seller's stock and passed to the purchaser's hands, they were not in themselves restricted commodities, incapable of further legal use except by compliance with rigid regulations, such as apply to morphine sulphate. The difference is like that between toy pistols or hunting rifles and machine guns. All articles of commerce may be put to illegal ends. But all do not have inherently the sam susceptibility to harmful and illegal use. Nor, by the same token, do all embody the same capacity, from their very nature, for giving the seller notice the buyer will use them unlawfully. Gangsters, not hunters or small boys, comprise the normal private market for machine guns. So drug addicts furnish the normal outlet for morphine which gets outside the restricted channels of legitimate trade. [319 U.S. 703, 711] This difference is important for two purposes. One is for making certain that the seller knows the buyer's intended illegal use. The other is to show that by the sale he intends to further, promote and cooperate in it. This intent, when given effect by overt act, is the gist of conspiracy. While it is not identical with mere knowledge that another purposes unlawful action, it is not unrelated to such knowledge. Without the knowledge, the intent cannot exist. United States v. Falcone, supra. 7 Furthermore, to establish the intent, the evidence of knowledge must be clear, not equivocal. Ibid, This, because charges of conspiracy are not to be made out by piling inference upon inference, thus fashioning what, in that case, was called a dragnet to draw in all substantive crimes.

The difference between sugar, cans, and other articles of normal trade, on the one hand, and narcotic drugs, machine guns and such restricted commodities, on the other, arising from the latters' inherent capacity for harm and from the very fact they are restricted, makes a difference in the quantity of proof required to show knowledge that the buyer will utilize the article unlawfully. Additional facts, such as quantity sales, high pressure sales methods, abnormal increases in the size of the buyer's purchases, etc., which would be wholly innocuous or not more than ground for suspicion in relation to unrestricted goods, may furnish conclusive evidence, in respect to restricted articles, that the seller knows the buyer has an illegal object and enterprise. Knowledge, equivocal and uncertain as to one, becomes sure as to the other. So far as knowl- [319 U.S. 703, 712] edge is the foundation of intent, the latter thereby also becomes the more secure.

The difference in the commodities has a further bearing upon the existence and the proof of intent. There may be circumstances in which the evidence of knowledge is clear, yet the further step of finding the required intent cannot be taken. Concededly, not every instance of sale of restricted goods, harmful as are opiates, in which the seller knows the buyer intends to use them unlawfully, will support a charge of conspiracy. 8 But this is not to say that a seller of harmful restricted goods has license to sell in unlimited quantities, to stimulate such sales by all the high-pressure methods, legal if not always appropriate, in the sale of free commodities; and thereby bring about subversion of the other forms, which otherwise would protect him, and violation of the Act's other restrictions. Such a view would assume that the market for opiates may be developed as any other market. But that is not true. Mass advertising and bargain counter discounts are not appropriate to commodities so surrounded with restrictions. They do not create new legal demand and new classes of legitimare patrons, as they do for sugar, tobacco and other free commodities. Beyond narrow limits, the normal legal market for opiates is not capable of being extended by such methods. The primary effect is rather to create black markets for dope and to increase illegal demand and consumption. [319 U.S. 703, 713] When the evidence discloses such a system, working in prolonged cooperation with a physician's unlawful purpose to supply him with his stock in trade for his illicit enterprise, there is no legal obstacle to finding that the supplier not only knows and acquiesces, but joins both mind and hand with him to make its accomplishment possible. The step from knowledge to intent and agreement may be taken. There is more than suspicion, more than knowledge, acquiescence, carelessness, indifference, lack of concern. There is informed and interested cooperation, stimulation, instigation. And there is also a 'stake in the venture' which, even if it may not be essential, is not irrelevant to the question of conspiracy. 9 Petitioner's stake here was in making the profits which it knew could come only from its encouragement of Tate's illicit operations. In such a posture the case does not fall doubtfully outside either the shadowy border between lawful co-operation and criminal association or the no less elusive line which separates conspiracy from overlapping forms of criminal cooperation.

Unless, therefore, petitioner has been exempted arbitrarily by the statute's terms, the evidence clearly was sufficient to sustain its conviction for conspiring with Tate. Its position here comes down ultimately to the view alluded to above that the statute has, in fact, thus immunized its action. In effect this means the only restriction imposed upon it, apart from other provisions not now material, such as those affecting registration, was the requirement it should receive from purchasing physicians a signed order form for each sale. That done, in its view, its full duty to the law was fulfilled, it acquired a complete immunity, and what the physician had done [319 U.S. 703, 714] or might do with the drugs became of no further concern to itself. Such a view would legalize an express written agreement between a registered wholesaler and a physician for the former to supply him with all his requirements for drugs for both legal and illegal distribution, conditioned only upon his using the required order forms. The statute contains no such exemption in explicit terms. Nor was one implied. 10

This being true, it can make no difference the agreement was a tacit understanding, created by a long course of conduct and executed in the same way. 11 Not the form or manner in which the understanding is made, but the fact of its existene and the further one of making it effective by overt conduct are the crucial matters. The proof, by the very nature of the crime, must be circumstantial12 and therefore

inferential to an extent varying with the conditions under which the crime may be committed. But this does not mean either that the evidence may be equivocal or that petitioner is exempt from its effects when it is not so, merely because in the absence of excesses such as were committed and in other circumstances the order form would have given it protection. It follows the mere fact that none of petitioner's representatives ever met Dr. Tate face to face or held personal communion with him is immaterial. Conspiracies, in short, can be committed by mail and by mail-order houses. This is true, n twithstanding the overt acts consist solely of sales, which but for their volume, frequency and prolonged [319 U.S. 703, 715] repetition, coupled with the seller's unlawful intent to further the buyer's project, would be wholly lawful transactions.

Accordingly, the judgment is

Affirmed.

Footnotes

[Footnote 1] The conspiracy statute, R.S. 5440, as amended, 18 U.S.C. 88, provides:

> 'If two or more persons conspire either to commit any offense against the United States, or to defraud the United States in any manner or for any purpose, and one or more of such parties do any act to effect the object of the conspiracy, each of the parties to such conspiracy shall be fined not more than $10,000, or imprisoned not more than two years, or both.'

The pertinent provisions of the Harrison Act are set out in note 3, infra.

[Footnote 2] 38 Stat. 785, as amended, 26 U.S.C. 3220, 3221.

[Footnote 3] 38 Stat. 785, as amended, 26 U.S.C. 2553, 2554. The indictment charged the conspiracy's object was to violate those portions of the Act (as amended) which provide:

> 'It shall be unlawful for any person required to register under the provisions of this part or section 2551(a) to import, manufacture, produce, compound, sell, deal in, dispense, distribute, administer, or give away any of the aforesaid drugs without having registered and paid the special tax as imposed by this part, or section 2551(a).' 26 U.S.C. 3224.
>
> 'It shall be unlawful for any person to purchase, sell, dispense, or distribute any of the drugs mentioned in section 2550(a) except in the original stamped package or from the original stamped package ....' 26 U. S.C. 2553.
>
> 'It shall be unlawful for any person to sell, barter, exchange, or give away any of the drugs mentioned in section 2550(a) except in pursuance of a written order of the person to whom such article is sold, bartered, exchanged, or given, on a form to be issued in blank for that purpose by the Secretary.' 26 U.S.C. 2554(a).
>
> 'It shall be unlawful for any person to obtain by means of said order forms any of the aforesaid drugs for any purpose other than the use, sale, or distribution thereof by him in the conduct of a lawful business in said drugs or in the legitimate practice of his profession.' 26 U.S.C. 2554(g).

[Footnote 4] Thus, although there were more than 1350 wholesale drug dealers in the United States from whom physicians might order narcotics (Traffic in Opium and Other Dangerous Drugs for the Year Ended December 31, 1941, United States Treasury, Bureau of Narcotics), about 27% of the 204 doctors convicted were petitioner's customers.

[Footnote 5] Testimony in the record establishes that the practice in the profession is to give one-eighth or one-fourth grain doses, and only rarely one-half grain doses. Cf. United States v. Behrman, 258 U.S. 280, 289 , 42 S.Ct. 303, 305. Furthermore, there was expert testimony to the effect that codein may be, and preferably is, used for the same medical purposes as morphine sulphate. During the period from 1934 to 1940, however, the record does not show that Tate ever ordered codein from petitioner.

[Footnote 6] R.S. 5323, 18 U.S.C. 550.

[Footnote 7] Although this principle was there applied to aiding and abetting a conspiracy among others, it has at least equal force in a situation where the charge is conspiring with another to further his unlawful conduct, without reference to any conspiracy between him and third persons.

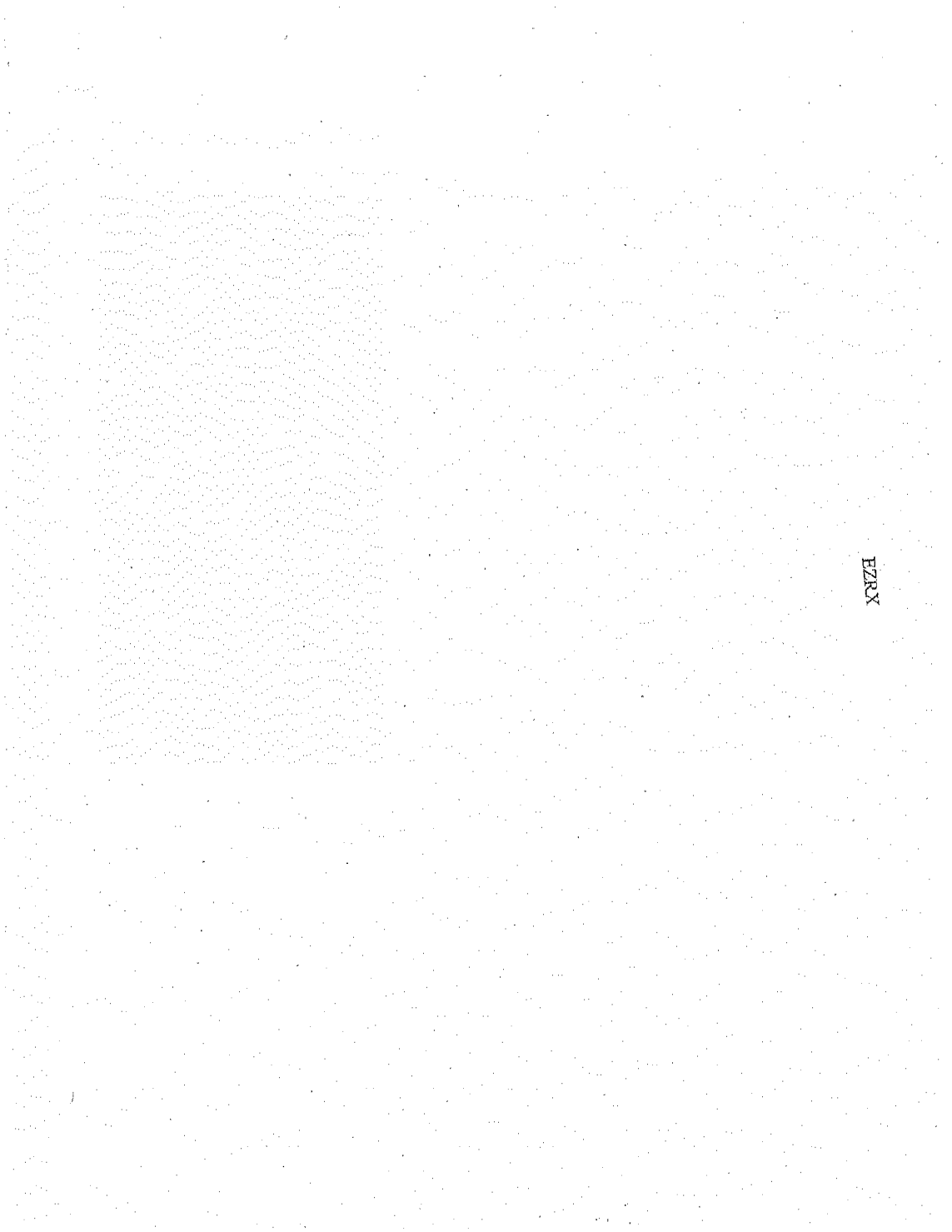
[Footnote 8] This may be true, for instance, of single or casual transactions, not amounting to a course of business, regular, sustained and prolonged, and involving nothing more on the seller's part than indifference to the buyer's illegal purpose and passive acquiescence in his desire to purchase, for whatever end. A considerable degree of carelessness coupled with casual transactions is tolerable outside the boundary of conspiracy. There may be also a fairly broad latitude of immunity for a more continuous course of sales, made either with strong suspicion of the buyer's wrongful use or with knowledge, but without stimulation or active incitement to purchase.

[Footnote 9] Cf. United States v. Falcone, 2 Cir., 109 F.2d 579, 581; and compare Backun v. United States, 4 Cir., 112 F.2d 635, 637; United States v. Harrison, 3 Cir., 121 F.2d 930, 933; United States v. Pecoraro, 2 Cir., 115 F.2d 245, 246.

[Footnote 10] Cf. Gebardi v. United States, 287 U.S. 112 , 53 S.Ct. 35, 84 A.L.R. 370; see also 81 U. of Pa.L.Rev. 474.

[Footnote 11] Glasser v. United States, 315 U.S. 60, 80 , 62 S.Ct. 457, 469; United States v. Manton, 107 F.2d 834, 839; United States v. Harrison, 3 Cir., 121 F.2d 930, 934; Eastern States Retail Lumber Dealers' Ass'n v. United States, 234 U.S. 600 , 34 S.Ct. 951, L.R.A. 1915A, 788; Interstate Circuit, Inc., v. United States, 306 U.S. 208 , 59 S. Ct. 467.

[Footnote 12] Ibid.



EZRX

Registrant Actions - 2004

FR Doc 04-24235 [Federal Register: October 29, 2004 (Volume 69, Number 209)] [Notices] [Page 63178-63182] From the Federal Register Online via GPO Access [wais.access.gpo.gov] [DOCID:fr29oc04-105]

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

EZRX, LLC Revocation of Registration

On May 17, 2004, the Deputy Administrator of the Drug Enforcement Administration (DEA) issued an Order to Show Cause and Immediate Suspension of Registration to EXRX, LLC (EZRX) of Union, New Jersey. EZRX was notified of an opportunity to show cause as to why DEA should not revoke its DEA Certificate of Registration, BE8488783, as a retail pharmacy, and deny any pending applications for renewal or modification of such registration pursuant to 21 U.S.C. 823(f) and 824(a)(4) for reason that its continued registration would be inconsistent with the public interest. EZRX was further notified that its DEA registration was immediately suspended as an imminent danger to the public health and safety pursuant to 21 U.S.C. 824(d).

The Order to Show Cause and Immediate Suspension alleged in sum, that EZRX was engaged in illegally dispensing controlled substances as part of a scheme in which controlled substances were dispensed by EZRX based on Internet orders placed by customers and approved by associated physicians, based solely on their review of Internet questionnaires and without personal contact, examination or bona fide physician/patient relationships. Such prescriptions were not issued ``in the usual course of professional treatment'' and violated 21 CFR 1306.04 and 21 U.S.C. 841(a). This action was part of a nationwide enforcement operation by DEA titled Operation Pharmnet, which targeted online suppliers of prescription drugs, including owners, operators, pharmacists and doctors, who have illegally and unethically been marketing controlled substances via the Internet.

According to the investigative file on May 26, 2004, the Order to Show Cause and Immediate Suspension of Registration was personally served by Special Agents and Diversion Investigators of the DEA at EZRX's registered premises in Union, New Jersey. More than thirty days have passed since the Order to Show Cause

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and Immediate Suspension of Registration was served on EZRX and DEA has not received a request for

hearing or any other reply from EZRX or anyone purporting to represent it in this matter.

Therefore, the Deputy Administrator of DEA, finding that (1) thirty days having passed since the delivery of the Order to Show Cause and Immediate Suspension of Registration to EZRX, and (2) no request for hearing having been received, concludes that EZRX is deemed to have waived its hearing right. See David W. Linder, 67 FR 12,579 (2002). After considering material from the investigative file in this matter, the Deputy Administrator now enters her final order without a hearing pursuant to 21 CFR 1301.43(d) and (e) and 1301.46.

The Deputy Administrator finds EZRX is currently registered with DEA as a retail pharmacy under DEA Registration, BE8488783 to dispense Schedule II through V Controlled Substances. That registration expires on August 31, 2006. The owners of EZRX are Frank C. Hernandez and his wife, Amada Hernandez.

In 2003, the DEA Miami Field Division initiated regulatory investigations of C&H Wholesale, Inc. (C&H) and Lifeline Pharmacy, Inc. (Lifeline). C&H was registered with DEA as a distributor of Schedule II through V controlled substances and Lifeline was registered as a retail pharmacy of the same substances. Both companies are owned by Mr. and Mrs. Hernandez and the registered premises they occupy are physically connected and share floor space with the Hernandez' non-drug businesses.

During the regulatory examination of C&H, it was discovered that C&H was distributing controlled substances almost exclusively to South Florida pharmacies, including Lifeline, which were filling Internet controlled substance prescriptions. The majority of distributions were for Schedule III and IV controlled substance weight loss medications including, but not limited to substantial quantities of phentermine, phendimetrazine tartrate, Dexedrine and tenuate.

On October 10, 2003, as a result of investigative findings that C&H and Lifeline were facilitating and dispensing controlled substances by virtue of prescriptions issued not for legitimate medical purposes and not in the usual course of professional medical practice, the then- Acting Deputy Administrator issued orders to show cause to C&H and Lifeline and immediately suspended their registrations on grounds that the posed an immediate threat to the public health and safety.

Subsequent investigation by Miami DEA investigators revealed that on August 21, 2003, the same day a federal search warrant was being executed on Lifeline's Florida premises, Mr. Hernandez filed a new application for registration on behalf of EZRX, as a retail pharmacy in New Jersey. That application was inadvertently routinely processed in New Jersey while the Miami investigation was still in process and it was approved on September 9, 2003. Later, in the course of document review, DEA Miami investigators found paperwork indicating Mr. and Mrs. Hernandez were the owners of EZRX and that two Florida employees, Mr. Hernandez' nephew and wife, were also key employees of the New Jersey retail pharmacy.

On November 6, 2003, DEA Miami investigators made an undercover buy from a Florida-based website. Using a fictitious name and an undercover Internet e-mail account and computer, investigators placed an order for Bontril, a Schedule IV controlled substance weight loss medication. After filling out a medical questionnaire on the website and sending a money order to an affiliated company, E.V.A. Global, Inc., a package was received at the undercover address via Federal Express. It was shipped by EZRX on November 11, 2003, from its registered address and contained 89 Bontril SR 105mg capsules. The prescription label indicated it had been dispensed by EZRX and the issuing physician was an individual, later identified as a DEA registrant, who had prescribed controlled substances during similar undercover purchases made through Lifeline. There was no contact between the prescribing physician and the undercover investigator, other than transmission of the Internet questionnaire.

Another physician involved with Internet prescribing thorough E.V.A. Global, Inc. was interviewed by investigators and described the process. He would access a web site provided him by E.V.A. Global, Inc., where customers' medical questionnaires would be posted. The physician would access the questionnaires one at a time, review the questionnaire and either approve or deny the prescription request. He did not

have the ability to suggest an alternative drug or an alternate amount and there was never any contact between the physician and either the ``patient'' or the dispensing pharmacy.

It was determined that from September through November 2003, EZRX ordered in excess of 300,000 dosage units of Schedule III and IV controlled substances, including the controlled substances commonly sold through websites affiliated with E.V.A. Global, Inc., to include phentermine, Ionamin, Meridia, Didrex, phendimetrazine tartrate and Ambien.

The Controlled Substances Act (CSA) establishes a ``closed system'' of distribution that regulates the movement of controlled substance prescription medications from importation or manufacture through their delivery to the ultimate user patient via the dispensing, administering or prescribing, pursuant to the lawful order of a practitioner. The regulations implementing the CSA explicitly describe the parameters of a lawful prescription as follows: ``A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a).

Prescriptions issued not in the ``usual course of professional treatment'' are not ``prescriptions'' for purposes of the CSA and individuals issuing and filling such purported prescriptions are subject to the penalties for violating the CSA's controlled substances provisions.

In United States v. Moore, 423 U.S. 122 (1975), the Supreme Court held that, ``Implicit in the registration of a physician is the understanding that he is authorized only to act `as a physician'.'' Id., at 141. In Moore the court implicitly approved a jury instruction that acting ``as a physician'' is acting ``in the usual course of a professional practice and in accordance with a standard of medical practice generally recognized and accepted in the United States.'' Id., at 138-139; see, United States v. Norris, 780 F.2d 1207, 1209 (5th Cir. 1986). Responsible professional organizations have issued guidance in this area. The American Medical Association's guidance for physicians on the appropriate use of the Internet in prescribing medication (H-120.949 Guidance for Physicians on Internet Prescribing) states:

``Physicians who prescribe medications via the Internet shall establish, or have established, a valid patient-physician relationship, including, but not limited to, the following components. The physician shall:

i. Obtain a reliable medical history and perform a physical examination of the patient, adequate to establish the diagnosis for which the drug is being prescribed and to identify underlying

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conditions and/or contraindications to the treatment recommended/ provided;

ii. Have sufficient dialogue with the patient regarding treatment options and the risks and benefits of treatment(s);

iii. As appropriate, follow up with the patient to assess the therapeutic outcome;

iv. Maintain a contemporaneous medical record that is readily available to the patient and, subject to the patient's consent, to his or her other health care professionals; and

v. Include the electronic prescription information as part of the patient medical record.''

In April 2000, the Federation of State Medical Boards adopted Model Guidelines for the Appropriate use of the Internet in Medical Practice, which states, in pertinent part, that:

Treatment and consultation recommendations made in an online setting, including issuing a prescription via electronic means, will be held to the same standards of appropriate practice as those in traditional (face-to-

face) settings. Treatment, including issuing a prescription, based solely on an online questionnaire or consultation does not constitute an acceptable standard of care.

The CSA regulations establish certain responsibilities not only on individual practitioners who issue prescriptions for controlled substances, but also on pharmacists who fill them. A pharmacist's ``corresponding responsibility'' regarding the proper dispensing of controlled substances is explicitly described in 21 CFR 1306.04(a). It provides:

A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.

In an April 21, 2001, policy statement, entitled, Dispensing and Purchasing Controlled Substances Over the Internet, 66 FR 21,181 (2001), DEA delineated certain circumstances in which prescribing over the Internet is unlawful. The policy provides, inter alia, that a controlled substance should not be issued or dispensed unless there was a bona fide doctor/patient relationship. Such a relationship required that the patient has a medical complaint, a medical history be taken, a physical examination performed, and some logical connection exists between the medical complaint, the medical history, the physical examination, and the drug prescribed. The policy statement specifically explained that the completion of ``a questionnaire that is then review by a doctor hired by the Internet pharmacy could not be considered the basis for a doctor/patient relationship * * * '' Id., at 21,182-21,183.

Rogue Internet Pharmacies bypass a legitimate doctor-patient relationship, usually by use of a cursory and incomplete online questionnaire or perfunctory telephone ``consult'' with a doctor, who usually has a contractual arrangement with the online pharmacy and is often paid on the basis of prescriptions issued. The Food and Drug Administration (FDA) considers the questionnaire, in lieu of face-to- face interaction, to be a practice that undermines safeguards of direct medical supervision and amounts to substandard medical care. See U.S. Food and Drug Administration, Buying Medicines and Medical Products Online, General FAQs (http://fda.gov/oc/buyonline/default.htm).

The National Association of Boards of Pharmacy considers internet pharmacies to be suspect if:

They dispense prescription medications without requiring the consumer to mail in a prescription, and if they dispense prescription medications and do not contact the patient's prescriber to obtain a valid verbal prescription. Further, online pharmacies are suspect if they dispense prescription medications solely based upon the consumer completing an online questionnaire without the consumer having a pre-existing relationship with a prescriber and the benefit of an in-person physical examination. State boards of pharmacy, boards of medicine, the FDA, as well as the AMA, condemn this practice and consider it to be unprofessional.

See, National Association of Boards of Pharmacy, VIPPS Program, Most Frequently Asked Questions (http://www.nabp.net/vipps/consumer/faq.asp).

Rogue Internet pharmacies often use persons with limited or no knowledge of medications and standard pharmacy practices to fill prescriptions, do not advertise the availability of pharmacists for medication consultation, and focus on select medications, usually lifestyle, obesity and pain medications. Rogue Internet pharmacies generally do not protect the integrity of original faxed prescriptions by requiring that they be received directly from the prescriber (not the patient) and do not verify the authenticity of suspect prescriptions.

When the established safeguards of an authentic doctor-patient relationship are lacking, controlled substance prescription drugs can not only be misused, but also present potentially serious health risks to patients. Rogue Internet pharmacies facilitate the easy circumvention of legitimate medical practice. The

FDA has stated:

We know that adverse events are under-reported and we know from history that tolerating the sale of unproven, fraudulent, or adulterated drugs results in harm to the public health. It is reasonable to expect that the illegal sales of drugs over the Internet and the number of resulting injuries will increase as sales on the Internet grow. Without clear and effective law enforcement, violators will have no reason to stop their illegal practices. Unless we begin to act now, unlawful conduct and the resulting harm to consumers most likely will increase.

See U.S. Food and Drug Administration, Buying Medicines and Medical Products Online, General FAQs (http://fda.gov/oc/buyonline/default.htm).

Pursuant to 21 U.S.C. 823(f) and 824(a)(4), the Deputy Administrator may revoke a DEA Certificate of Registration and deny any pending application for renewal of such registration, if she determines that the continued registration would be inconsistent with the public interest. Section 823(f) requires that the following factors be considered in determining the public interest:

(1) The recommendation of the appropriate state licensing board or professional disciplinary authority.
(2) The applicant's experience in dispensing or conducting research with respect to controlled substances.
(3) The applicant's conviction record under federal or state laws relating to the manufacture, distribution, or dispensing of controlled substances.
(4) Compliance with applicable state, federal, or local laws relating to controlled substances.
(5) Such other conduct which may threaten the public health or safety.

These factors are to be considered in the disjunctive; the Deputy Administrator may rely on any one or a combination of factors and may give each factor the weight she deems appropriate in determining whether a registration should be revoked or an application for registration denied. See Henry J. Schwartz, Jr., M.D., 54 FR 16,422 (1989).

In this case, the Deputy Administrator finds factors two, four and five relevant to a determination of whether EZRX's continued registration remains consistent with the public interest.

With regard to factor one, the recommendation of the appropriate state licensing board or professional disciplinary authority, there is no evidence in the investigative file that EZRX has been the subject of a state disciplinary proceeding, nor is there

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evidence demonstrating that its state pharmacy license or state controlled substance authority are currently restricted in any form. Nevertheless, state licensure is a necessary, but not sufficient condition for registration, and therefore, this factor is not dispositive. See e.g., Wesley G. Harline, M.D., 65 FR 5,665-01 (2000); James C. LaJevic, D.M.D., 64 FR 55,962 (1999).

With regard to factors two and four, the Deputy Administrator finds that the primary conduct at issue in this proceeding (i.e., the unlawful dispensing of controlled substance prescriptions for use by Internet customers) relates to both EZRX's and its owners' experience in dispensing controlled substances, as well as its compliance with applicable state, federal, or local laws relating to controlled substances. DEA has consistently held that the registration of a pharmacy may be revoked as the result of the unlawful activity of the pharmacy's owners, majority shareholders, officers, managing pharmacist or other key employee. See Plaza Pharmacy, 53 FR 36,910 (1988)

A DEA registration authorizes a physician to prescribe or dispense controlled substances only within the usual course of his or her professional practice. For a prescription to have been issued within the course of a practitioner's professional practice, it must have been written for a legitimate medical purpose within the context of a valid physician-patient relationship. See Mark Wade, M.D., 69 FR 7,018 (2004). 51,600 (1998).

Legally, there is absolutely no difference between the sale of an illicit drug on the street and the illicit dispensing of a licit drug by means of a physician's prescription. See Floyd A Santner, M.D., 55 FR 37,581 (1990).

Factors two and four are relevant to EZRX's dispensing of Internet prescribed controlled substances. The Deputy Administrator concludes from a review of the record that the physicians issuing these prescriptions did not establish valid physician-patient relationships with Internet customers to whom they prescribed controlled substances. DEA has previously found that prescriptions issued through a pharmacy Internet Web site are not considered as having been issued in the usual course of medical practice, in violation of 21 CFR 1306.04 and has revoked the DEA registrations of several physicians for participating in Internet prescribing schemes similar to or identical to that of EZRX. See, Marvin L. Gibbs, Jr., M.D., 69 FR 11,658 (2004); Mark Wade, M.D., supra, 69 FR 7,018; Ernesto A. Cantu, M.D., 69 FR 7,104-02 (2004); Rick Joe Nelson, M.D., 66 FR 30,752 (2001).

Similarly, in the past few years, DEA has issued orders to show cause and subsequently revoked the DEA registrations of pharmacies which failed to fulfill their corresponding responsibility in Internet prescribing operations, similar to those of EZRX and its principals and their affiliated companies. See Prescriptiononline.com, 69 FR 5,583 (2004); Pill Box Pharmacy (surrendered DEA registration as part of owner's and pharmacy's guilty plea to 21 U.S.C. 841(a)(1) violation); Friendly Pharmacy (pharmacist pled guilty and owner convicted at trial, of violating 21 U.S.C. 841(a). Indeed, C&H and Lifeline, the predecessor Internet pharmacy entities owned by EZRX's principals, were both subjects of orders to show cause with immediate suspensions and both companies surrendered their DEA Certificates of Registration.

In the instant case, physicians associated with the Internet operation authorized prescriptions for controlled substances without the benefit of face-to-face physician-patient contact, physical exam or medical test. There is no information in the investigative file demonstrating that the issuing physicians even took the time corroborate responses to questionnaires that were submitted by EZRX's customers. Here, it is clear that the issuance of controlled substance prescriptions to persons whom the prescribing physician has not established a valid physician-patient relationship is a radical departure from the normal course of professional practice and that EZRX knowingly participating in this scheme.

With regard to factor three, applicant's conviction record under federal or state laws relating to the dispensing of controlled substances, the record does not reflect that EZRX or its principals have been convicted of a felony related to controlled substances.

Regarding factor five, such other conduct which may threaten the public health or safety, the Deputy Administrator finds this factor relevant to EZRX's continued dispensing to Internet customers after issuance of policy statements designed to assist licensed practitioners and pharmacists in the proper prescribing and dispensing of dangerous controlled drugs.

Factor five is also relevant to EZRX's continued Internet prescribing after C&H and Lifeline, both owned by the principals of EZRX, were served with Orders to Show Cause and for Immediate Suspensions in October 2003. These entities sought an order in United States District Court seeking to restrain DEA from imposing the immediate suspensions of their registrations. After the District Court held hearings to make a threshold determination that DEA had some basis to back up its allegations regarding the Internet prescribing activities of C&H and Lifeline, the Court upheld the immediate suspensions by DEA, finding ``there is not a substantial likelihood that C&H and Lifeline will prevail on the merits.'' It further stated, ``the danger of the public obtaining controlled substances outweighs the threatened injury to C&H and Lifeline. Granting the preliminary injunction would affect the public interest, again putting the public in danger of obtaining controlled substances.'' See C&H Wholesale, Inc. and Lifeline Pharmacy, Inc., CIV 03-61910 (S.D. Fla., October 23, 2003). Nevertheless after the District Court's Order, EZRX continued this practice and dispensed the controlled substance ordered over the Internet by undercover agents on November 6, 2003.

Similarly, factor five is relevant to Mr. Hernandez' timing in applying for EZRX's DEA registration on August 21, 2003. This is the date a federal search warrant was executed on Lifeline, his Florida pharmacy and

further suggests the New Jersey operation was established by Mr. Hernandez to continue Internet dispensing as a back up to his Florida operations.

The Deputy Administrator has previously expressed her deep concern about the increased risk of diversion which accompanies Internet controlled substance transactions. Given the nascent practice of cyber-distribution of controlled drugs to faceless individuals, where interaction between individuals is limited to information on a computer screen or credit card, it is virtually impossible to insure that these highly addictive, and sometimes dangerous products will reach the intended recipient, and if so, whether the person purchasing these products has an actual need for them. The ramifications of obtaining dangerous and highly addictive drugs with the ease of logging on to a computer and the use of a credit card are disturbing and immense, particularly when one considers the growing problem of the abuse of prescription drugs in the United States. See, Mark Wade, M.D., supra, 69 FR 7,018.

The Deputy Administrator has also previously found that in a 2001 report, the National Clearinghouse for Alcohol and Drug Information estimated that 4 million Americans ages 12 and older had acknowledged misusing

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prescription drugs. That accounts for 2% to 4% of the populations--a rate of abuse that has quadrupled since 1980. Prescription drug abuse-- typically of painkillers, sedatives and mood-altering drugs--accounts for one-third of all illicit drug use in the United States. See Mark Wade, M.D., supra, 69 FR 7,018.

The Deputy Administrator finds that with respect to Internet transactions involving controlled substances, the horrific untold stories of drug abuse, addiction and treatment are the unintended, but foreseeable consequence of providing highly addictive drugs to the public without oversight. The closed system of distribution, brought about by the enactment of the Controlled Substances Act, is completely compromised when individuals can easily acquire controlled substances without regard to age or health status. Such lack of oversight describes EZRX, its principals, their associated companies and affiliated physician's practice of issuing prescriptions for and distributing controlled substances to indistinct Internet customers. Such conduct contributes to the abuse of controlled substances by EZRX's customers and is relevant under factor five and further supports revocation of its DEA Certificate of Registration.

It appears that EZRX and its principals, motivated purely by profit and in pursuit of financial gain, have demonstrated a cavalier disregard for controlled substance laws and regulations and a disturbing indifference to the health and safety of customers who purchased dangerous drugs through the Internet. Such demonstrated lack of character and adherence to the responsibilities inherent in a DEA registration show in no uncertain terms that EZRX's continued registration with DEA would be inconsistent with the public interest.

Accordingly, the Acting Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in her by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b) and 0.104, hereby orders that DEA Certificate of Registration BE8488783, previously issued to EZRX, LLC, be, and it hereby is, revoked. The Deputy Administrator further orders that any pending applications for renewal of such registration be, and they hereby are, denied. This order is effective November 29, 2004.

Dated: September 29, 2004.

Michele M. Leonhart,
Deputy Administrator.

[FR Doc. 04-24235 Filed 10-28-04; 8:45 am]

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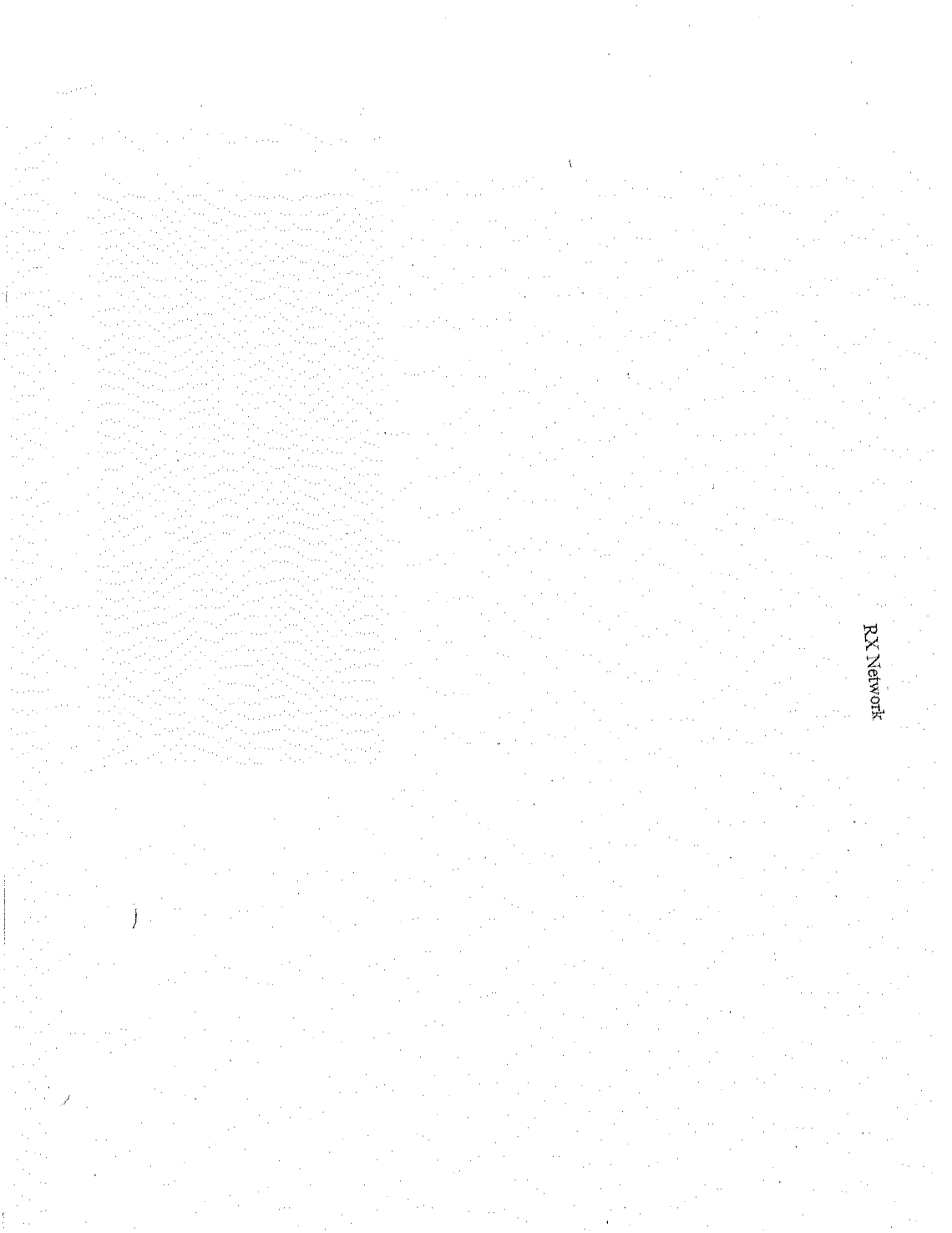
RX Network

Registrant Actions - 2004

FR Doc 04-23715 [Federal Register: October 22, 2004 (Volume 69, Number 204)] [Notices] [Page 62093-62095] From the Federal Register Online via GPO Access [wais.access.gpo.gov] [DOCID:fr22oc04-112]

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Docket No. 04-01]

RX Network of South Florida, LLC Revocation of Registration

On October 10, 2003, the then-Acting Deputy Administrator of the Drug Enforcement Administration (DEA),

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issued an Order to Show Cause and Immediate Suspension of Registration to RX Network of South Florida, LLC (Respondent), notifying it of an opportunity to show cause as to why DEA should not revoke its DEA Certificate of Registration, BR7139238, as a retail pharmacy, and deny any pending applications for renewal or modification of registration pursuant to 21 U.S.C. 823(f) and 824(a)(4), for reason that Respondent's continued registration would be inconsistent with the public interest.

The Order to Show Cause and Immediate Suspension of Registration further informed Respondent of the suspension of its DEA Certificate of Registration, as an imminent danger to the public health or safety pursuant to 21 U.S.C. 824(d). The Order to Show Cause and Immediate Suspension of Registration alleged in relevant part, that Respondent, owned and operated by Vincent Chhabra, Sabrina Faruqui and Carleta Carolina, dispensed over 19,300,000 various controlled substances through orders of customers who had accessed an Internet Web site set up by Respondent. Customers of Respondent would complete a questionnaire set up on the Web site, which solicited information about the customer, including the type of medication desired. After the customer's credit card was processed, the questionnaire was forwarded to one of several "staff" physicians who then issued prescriptions for the controlled substances being ordered. The prescriptions were then sent electronically to Respondent, which then dispensed the controlled substances to customers through the mail. The "staff" physicians, as well as Respondent's customers, were located in various states

throughout the United States and the physicians had no interaction with customers before prescribing the controlled substances.

e Order to Show Cause and Immediate Suspension of Registration also alleged that on April 21, 001, DEA issued a policy statement, Dispensing and Purchasing Controlled Substances over the Internet, 66 FR 21,181 (2001). The policy statement delineated certain circumstances under the which DEA deems prescribing over the Internet to be unlawful, including, inter alia, the circumstance when a controlled substance is issued or dispensed without a bona fide doctor/patient relationship. The policy further explained that completed questionnaires, later reviewed by a doctor hired by the Internet pharmacy "could not be considered the basis of a doctor/patient relationship." Id., at 21,182-21,183. In further support of DEA policy, the Order to Show Cause and Immediate Suspension of Registration cited the final order revoking the DEA registration of a practitioner who had participated in an Internet pharmacy scheme similar to that of Respondent. See Rick Joe Nelson, M.D. 66 FR 30,752 (2001).

The Order to Show Cause and Immediate Suspension of Registration further referenced correspondence during November 2002 and February 2003 between the United States Department of Justice and the then- attorney of Vincent Chhabar. In those letters, Mr. Chhabra's attorney was reminded that his client had been notified of the foregoing DEA policy and requested to shut down its Internet pharmacy operation. The Order to Show Cause and Immediate Suspension of Registration further referenced an order of emergency suspension issued by the Florida Department of Health (the Department) against Respondent on May 30, 2002, as well as administrative complaints issued by the Department's Pharmacy Board against Respondent and one of its pharmacists. While both actions stemmed from allegations that Respondent operated an Internet pharmacy, the Order to Show Cause and Immediate Suspension of Registration referenced the Pharmacy Board's March 31, 2003, assessment of a $48,000 fine as the only sanction.

he Order to Show Cause and Immediate Suspension of Registration further alleged that on seven separated occasions during September and October 2003, DEA diversion investigators and agents from the United States Food and Drug Administration conducted a series of undercover operations with the objective of obtaining controlled substances from Respondent through its Internet operation. The operation resulted in law enforcement officers receiving quantities of Bontril (a Schedule III controlled substance) and phentermine (a Schedule IV controlled substance) from Respondent after filling out Internet questionnaires with fictitious names and fictitious weights. The law enforcement officers had no contact with the prescribing physicians, who issued prescriptions from locations in Florida, Missouri and Pennsylvania. However, there were no allegations in the Order to Show Cause and Immediate Suspension of Registration addressing the status of Respondent's authorization to handle controlled substances in the State of Florida.

By letter dated November 3, 2003, Respondent, through counsel, requested a hearing in this matter. The request included various arguments challenging the basis for the Order to Show Cause and Immediate Suspension of Registration. On November 10, 2003, Presiding Administrative Law Judge Mary Ellen Bittner (Judge Bittner) issued an Order for Prehearing Statements.

On November 21, 2003, in lieu of a prehearing statement, counsel for DEA filed Government's Motion for Summary Judgment and Motion to Stay the Filing of Prehearing Statements. In support of its motions, the Government referenced a letter dated November 20, 2003, in which Respondent's counsel had notified the Florida Board of Pharmacy of the following: "Without the ability to dispense ontrolled substance[s], a crucial element of operating a pharmacy, [Respondent] can no longer remain viable, and must relinquish its pharmacy permit." According to the Government, the letter indicated Respondent no longer had a pharmacy license in the State of Florida and, as a result, further proceedings in the matter were not required. Attached to the Government's motion was the

aforementioned letter from Respondent's counsel to the Florida Board of Pharmacy. In response to the Government's motion, Respondent argued in relevant part, that the Order to Show Cause and mediate Suspension of Registration had not alleged that it did not have a current state pharmacy ense. Respondent further argued that its lack of such a license now rendered these proceedings egally moot" and that the Administrative Law Judge should deny the Government's Motion for Summary Disposition and issue an order dismissing the case as moot.

On December 17, 2003, Judge Bittner issued her Opinion and Recommended Decision of the Administrative Law Judge (Opinion and Recommended Decision). As part of her recommended ruling, Judge Bittner rejected Respondent's contentions concerning the Government's failure to initially allege lack of state authority, holding the relevant question was Respondent's status to handle controlled substances at the time of the Opinion and Recommended Decision, not at what stage of the proceedings that status may have changed. She further noted Respondent had never surrendered its DEA Certificate of Registration and that the surrender of its state pharmacy license did not render this proceeding moot. Judge Bittner granted the Government's Motion for Summary Disposition, finding Respondent lacked authorization to handle controlled

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substances in Florida, the jurisdiction in which it is registered with DEA. In granting the Government's motion, Judge Bittner further recommended that Respondent's DEA registration be revoked and any pending applications be denied. According to the letter transmitting this matter to the Deputy Administrator, no exceptions were filed by either party to the Opinion and Recommended Decision.

The Deputy Administrator has considered the record in its entirety and pursuant to 21 CFR 1316.67, ereby issues her final order based upon the findings of fact and conclusions of law as hereinafter set orth. The Deputy Administrator adopts, in full, the Opinion and Recommenced Decision of the Administrative Law Judge.

The Deputy Administrator finds that Respondent currently possesses DEA Certificate of Registration RB7139238 and is registered to handle controlled substances in Florida as a retail pharmacy. The Deputy Administrator's review of the November 20, 2003, letter from Respondent's counsel to the Florida Board of Pharmacy reveals that after receiving the order of immediate suspension of its DEA registration, Respondent surrendered its pharmacy permit to the Board of Pharmacy. It appears from this action that Respondent surrendered its authority to handle controlled substances in Florida and, as a result, lacks a necessary prerequisite for DEA registration. There is no evidence before the Deputy Administrator that Respondent's pharmacy permit has been returned or reinstated or that Respondent is currently licensed in Florida as a retail pharmacy. Accordingly, it is reasonable to infer that Respondent is without authorization to handle controlled substances in that state.

DEA does not have statutory authority under the Controlled Substances Act to issue or maintain a registration if the applicant or registrant is without state authority to handle controlled substances in the state in which he conducts business. See 21 U.S.C. 802(21), 823(f) and 824(a)(3). This prerequisite has been consistently upheld. See Prescriptionline.com, 69 FR 5583 (2004); Graham Travers Schuler, M.D., 65 FR 50,570 (2000); Wingfield Drugs, Inc., 52 FR 27,070 (1987). The agency has also maintained this standard in matters involving the immediate suspension of a DEA Certificate of Registration under 21 U.S.C. 824(d). See Chemical Dependence Associates of Houston, 58 FR 37505 1993).

Here, Respondent is currently not licensed to handle controlled substances in Florida, the state where it maintains its registration with DEA. Therefore, Respondent is not entitled to maintain that registration.

Because Respondent is not entitled to a DEA registration in Florida due to its lack of state authorization to handle controlled substances, the Deputy Administrator concludes it is unnecessary to address whether Respondent's registration should be revoked based upon the public interest grounds asserted in the Order to Show Cause and Immediate Suspension of Registration. See Deanwood Pharmacy, 68 FR 41662 (2003); Nathaniel-Aikens-Afful, M.D., 62 FR 16871 (1997); Greenbelt Professional Pharmacy, 57 FR 55000 (1992).

Accordingly, the Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in her by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b) and 0.104, hereby orders that DEA Certificate of Registration, BR7139238, issued to RX Network of South Florida, LLC, be, and it hereby is, revoked. The Deputy Administrator further orders that any pending applications for renewal or modification of such registration be, and they hereby are, denied. This order is effective November 22, 2004.

Dated: October 5, 2004.

Michele M. Leonhart,
Deputy Administrator.

[FR Doc. 04-23715 Filed 10-21-04; 8:45 am]

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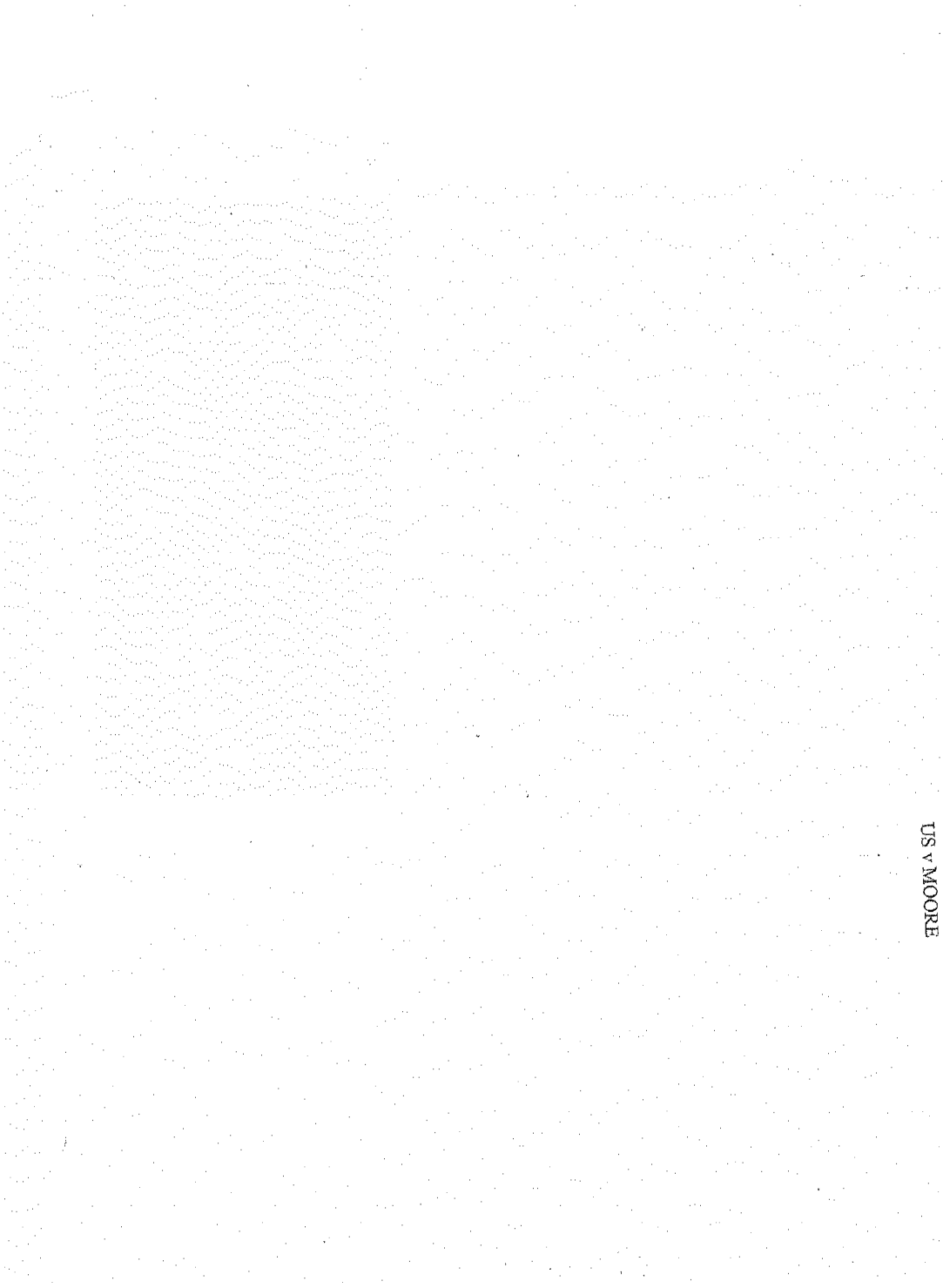


U.S. Supreme Court

UNITED STATES v. MOORE, 423 U.S. 122 (1975)

423 U.S. 122

UNITED STATES v. MOORE.
CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT.
No. 74-759.

Argued October 7, 1975
Decided December 9, 1975.

Respondent, a licensed physician registered under the Controlled Substances Act (CSA), 21 U.S.C. 801 et seq., was convicted of knowing and unlawful distribution and dispensation of methadone (a controlled substance or addictive drug used in the treatment of heroin addicts) in violation of 21 U.S.C. 841 (a) (1), which makes it unlawful for "any person" knowingly or intentionally to distribute or dispense a controlled substance, except as authorized by the CSA. The evidence disclosed that respondent prescribed large quantities of methadone for patients without giving them adequate physical examinations or specific instructions for its use and charged fees according to the quantity of methadone prescribed rather than fees for medical services rendered. The Court of Appeals, however, reversed the conviction on the grounds that respondent was exempted from prosecution under 841 by virtue of his status as a registrant and that a registrant can be prosecuted only under 842 and 843, which prescribe less severe penalties than 841. Held: Registered physicians can be prosecuted under 841 when, as here, their activities fall outside the usual course of professional practice. Pp. 131-145.

(a) Only the lawful acts of registrants under the CSA are exempted from prosecution under 841. That section by its terms reaches "any person" and does not exempt (as it could have) "all registrants" or "all persons registered under the Act." The language of the qualified authorization of 822 (b), which authorizes registrants to possess, distribute, or dispense controlled substances to the extent authorized by their registration and in conformity with other CSA provisions, and which was added merely to ensure that persons engaged in lawful activities could not be prosecuted, cannot be fairly read to support the view that all activities of registered physicians are beyond the reach of 841 simply because of their status. Pp. 131-133.

(b) There is no indication in the operative language of 841-843 that Congress intended to establish two mutually exclusive [423 U.S. 122, 123] penalty systems, with nonregistrants to be punished under 841 and registrants under 842 and 843, the fact that the term "registrants" is used in some subsections of 842 and 843 but not in 841 being of limited significance. Moreover, the legislative history indicates that Congress was concerned with the nature of the drug transaction, rather than with the defendant's status. Pp. 133-135.

(c) It is immaterial whether respondent also could have been prosecuted for the relatively minor offense of violating 829 with respect to the issuing of prescriptions, since there is nothing in the statutory scheme or the legislative history that justifies a conclusion that a registrant who may be prosecuted for violating 829 is thereby exempted from prosecution under 841 for the significantly greater offense of acting as a drug "pusher." Pp. 135-138.

(d) The scheme of the CSA, viewed against the background of the legislative history, reveals an intent to limit a registered physician's dispensing authority to the course of his "professional practice." Pp. 138-143.

(e) Congress was concerned that the drug laws not impede legitimate research and that physicians be allowed reasonable discretion in treating patients, but it did not intend to exempt from serious criminal penalties those acts by physicians that go beyond the limits of approved professional practice. Pp. 143-145.

(f) Where the statutory purpose is clear, the canon of strict construction of criminal statutes favoring the accused will be satisfied if the words of the statute are "given their fair meaning in accord with the manifest intent of the lawmakers." United States v. Brown, 333 U.S. 18, 25-26. P. 145.

164 U.S. App. D.C. 319, 505 F.2d 426, reversed and remanded.

POWELL, J., delivered the opinion for a unanimous Court.

Paul L. Friedman argued the cause for the United States. With him on the briefs were Solicitor General Bork, Assistant Attorney General Thornburgh, Acting Assistant Attorney General Keeney, and Sidney M. Glazer.

Raymond W. Bergan argued the cause for respondent. [423 U.S. 122, 124] With him on the brief were Edward Bennett Williams and Harold Ungar.

MR. JUSTICE POWELL delivered the opinion of the Court.

The issue in this case is whether persons who are registered under the Controlled Substances Act (CSA or Act), 84 Stat. 1242, 21 U.S.C. 801 et seq., can be prosecuted under 841 for dispensing or distributing controlled substances. The United States Court of Appeals for the District of Columbia Circuit reversed the conviction of respondent, a licensed physician registered under the Act, on the ground that he was exempted from prosecution under 841 by virtue of his status as a registrant. We reverse and hold that registered physicians can be prosecuted under 841 when their activities fall outside the usual course of professional practice.

I

Dr. Moore was charged, in a 639-count indictment, with the knowing and unlawful distribution and dispensation of methadone (Dolophine), a Schedule II controlled substance, 1 in violation of 21 U.S.C. 841 (a) (1). That subsection provides:

"Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally -

"(1) to manufacture, distribute, or dispense, or [423 U.S. 122, 125] possess with intent to manufacture, distribute, or dispense, a controlled substance . . . ."

The indictment covered a 5 1/2-month period from late August 1971 to early February 1972. It was reduced before trial to 40 counts, and the jury convicted respondent on 22 counts. He was sentenced to concurrent terms of five to 15 years' imprisonment on 14 counts, and to concurrent terms of 10 to 30 years on the remaining eight counts. The second set of sentences was to be consecutive with the first. Fines totaling $150,000 were also imposed. 2

Methadone is an addictive drug used in the treatment of heroin addicts. If taken without controls it can, like heroin, create euphoric "highs," but if properly administered it eliminates the addict's craving for heroin without providing a "high." The two principal methods of treating heroin addicts with methadone are "detoxification" and "maintenance." Under a maintenance program, the addict is given a fixed dose once a day for an indefinite period to keep him from using heroin. In detoxification the addict is given a large dose of methadone during the first few days of treatment to keep him free of withdrawal symptoms. Then the dose is gradually reduced until total abstinence is reached.

Maintenance is the more controversial method of treatment. During the period covered by the indictment, registration under 822, in itself, did not entitle a physician to conduct a maintenance program. In addition to a 822 registration, the physician who wished to conduct such a program was required to [423 U.S. 122, 126] obtain authorization from the Food and Drug Administration for investigation of a new drug. Dr. Moore's authorization by the FDA was revoked in the summer of 1971, and he does not claim that he was conducting an authorized maintenance program. Instead, his defense at trial was that he had devised a new method of detoxification based on the work of a British practitioner. He testified that he prescribed large quantities of methadone to achieve a "blockade" condition, in which the addict was so saturated with methadone that heroin would have no effect, and to instill a strong psychological desire for detoxification. The Government's position is that the evidence established that Dr. Moore's conduct was inconsistent with all accepted methods of treating addicts, that in fact he operated as a "pusher."

Respondent concedes in his brief that he did not observe generally accepted medical practices. He conducted a large-scale operation. Between September 1971 and mid-February 1972 three District of Columbia pharmacies filled 11,169 prescriptions written by Dr. Moore. These covered some 800,000 methadone tablets. On 54 days during that period respondent wrote over 100 prescriptions a day. In billing his patients he used a "sliding-fee scale" pegged solely to the quantity prescribed, rather than to the medical services performed. The fees ranged from $15 for a 50-pill prescription to $50 for 150 pills. In five and one-half months Dr. Moore's receipts totaled at least $260,000.

When a patient entered the office he was given only the most perfunctory examination. Typically this included a request to see the patient's needle marks (which in more than one instance were simulated) and an unsupervised urinalysis (the results of which were regularly ignored). A prescription was then written for the amount requested by the patient. On return visits - for [423 U.S. 122, 127] which appointments were never scheduled - no physical examination was performed and the patient again received a prescription for whatever quantity he requested. Accurate records were not kept, and in some cases the quantity prescribed was not recorded. There was no supervision of the administration of the drug. Dr. Moore's instructions consisted entirely of a label on the drugs reading: "Take as directed for detoxification." Some patients used the tablets to get "high"; others sold them or gave them to friends or relatives. Several patients testified that their use of methadone increased dramatically while they were under respondent's care. 3

The Court of Appeals, with one judge dissenting, assumed that respondent acted wrongfully but held that he could not be prosecuted under 841. 4 164 U.S. [423 U.S. 122, 128] App. D.C. 319, 505 F.2d 426 (1974). The court found that Congress intended to subject registered physicians to prosecution only under 842 and 843, 5 which prescribe [423 U.S. 122, 129] less severe penalties than 841. 6 The court reasoned:

> ". . . Congress intended to deal with registrants primarily [423 U.S. 122, 130] through a system of administrative controls, relying on modest penalty provisions to enforce those controls, and reserving the severe penalties provided for in 841 for those seeking to avoid regulation entirely by not registering." 164 U.S. App. D.C., at 323, 505 F.2d, at 430.

It said, further, that 842 and 843 were enacted to enforce that scheme, while 841 was reserved for

prosecution of those outside the "legitimate distribution chain." Persons registered under the Act were "authorized by [the] subchapter" within the meaning of 841 and thus were thought to be immunized against prosecution under that section. 7 [423 U.S. 122, 131]

Respondent advances two basic arguments, contending that each requires affirmance of the Court of Appeals: (i) as that court held, registered physicians may be prosecuted only under 842 and 843; and (ii) in any event, respondent cannot be prosecuted under 841 because his conduct was "authorized by [the] subchapter" in question. We now consider each of these arguments.

II

A

Section 841 (a) (1) makes distribution and dispensing of drugs unlawful "[e]xcept as authorized by this subchapter . . . ." Relying on this language, the Court of Appeals held that a physician registered under the Act is per se exempted from prosecution under 841 because of his status as a registrant. We take a different view and hold that only the lawful acts of registrants are exempted. By its terms 841 reaches "any person." It does not exempt (as it could have) "all registrants" or "all persons registered under this Act."

The Court of Appeals relied also on 822 (b), which provides: "Persons registered . . . under this subchapter to . . . distribute, or dispense controlled substances are authorized to possess, . . . distribute, or dispense such substances . . . to the extent authorized by their registration and in conformity with the other provisions of this subchapter." This is a qualified authorization of certain activities, not a blanket authorization of all acts by certain persons. This limitation is emphasized by the subsection's heading "Authorized activities," which parallels the headings of 841-843 "Unlawful acts." We think the statutory language cannot fairly be read to support the view that all activities of registered physicians [423 U.S. 122, 132] are exempted from the reach of 841 simply because of their status.

If 822 (b) were construed to authorize all such activities, thereby exempting them from other constraints, it would constitute a sharp departure from prior laws. But there is no indication that Congress had any such intent. Physicians who stepped outside the bounds of professional practice could be prosecuted under the Harrison Act (Narcotics) of 1914, 38 Stat. 785, the predecessor of the CSA. In Jin Fuey Moy v. United States, 254 U.S. 189 (1920), the Court affirmed the conviction of a physician on facts remarkably similar to those before us (e. g., no adequate physical examination, the dispensing of large quantities of drugs without specific directions for use, and fees graduated according to the amount of drugs prescribed). A similar conviction was upheld in United States v. Behrman, 258 U.S. 280 (1922), where the defendant-doctor had prescribed heroin, morphine, and cocaine to a person whom he knew to be an addict.

In enacting the CSA Congress attempted to devise a more flexible penalty structure than that used in the Harrison Act. H. R. Rep. No. 91-1444, Pt. 1, pp. 1, 4 (1970). 8 Penalties were geared to the nature of the violation, including the character of the drug involved. But the Act was intended to "strengthen," rather than to weaken, "existing law enforcement authority in the field of drug abuse." 84 Stat. 1236 (1970) (preamble). See also H. R. Rep. No. 91-1444, p. 1.

Section 822 (b) was added to the original bill at a late date 9 to "make it clear that persons registered under [423 U.S. 122, 133] this title are authorized to deal in or handle controlled substances." H. R. Rep. No. 91-1444, p. 38. It is unlikely that Congress would seek, in this oblique way, to carve out a major new exemption, not found in the Harrison Act, for physicians and other registrants. Rather, 822 (b) was added merely to ensure that persons engaged in lawful activities could not be prosecuted.

B

Respondent nonetheless contends that 841 and 822 (b) must be interpreted in light of a congressional intent to set up two separate and distinct penalty systems: Persons not registered under the Act are to be punished under 841, while those who are registered are to be subject only to the sanctions of 842 and 843. The latter two sections, the argument goes, establish modest penalties which are the sole sanctions in a system of strict administrative regulation of registrants.

The operative language of those sections provides no real support for the proposition that Congress intended to establish two mutually exclusive systems. It is true that the term "registrants" is used in 842 and 843, and not in 841. But this is of limited significance. All three sections provide that "[i]t shall be unlawful for any person . . . [to commit the proscribed acts]." Two of the eight subsections of 842 (a), one of the five subsections of 843 (a), and 842 (b) further qualify "any person" with "who is a registrant." The other subsections of 842 and 843 are not so limited. In context, "registrant" is merely a limiting term, indicating that the only "persons" who are subject to these subsections are "registrants." 10 There is no indication that "persons" [423 U.S. 122, 134] means "nonregistrants" when introducing the other subsections.

There are other indications that 841, and 842 and 843, do not constitute two discrete systems. Section 843 (b), for example, makes it unlawful for any person to use a communication facility in committing a felony under any provision of the subchapter. But violations of both 841 and 843 lead to felony convictions; criminal violations of 842 are misdemeanors. 11 842 (c) (2) (A), 802 (13); 18 U.S.C. 1. And counsel for respondent agreed at oral argument that registrants can be prosecuted under 841 (a) (2), which prohibits the creation, distribution, dispensing, or possession with intent to distribute or dispense of a "counterfeit substance."

The legislative history indicates that Congress was concerned with the nature of the drug transaction, rather than with the status of the defendant. The penalties now embodied in 841-843 originated in 501-503 of the Controlled Dangerous Substances Act of 1969. The Report of the Senate Judiciary Committee on that bill described 501 (the counterpart of 841) as applying to "traffickers." S. Rep. No. 91-613, p. 8 [423 U.S. 122, 135] (1969). Section 502 provided "[a]dditional penalties . . . for those involved in the legitimate drug trade," and "[f]urther penalties . . . for registrants" were specified in 503. S. Rep. No. 91-613, p. 9. The House Committee Report on the bill that was to become the CSA explains: "The bill provides for control . . . of problems related to drug abuse through registration of manufacturers, wholesalers, retailers, and all others in the legitimate distribution chain, and makes transactions outside the legitimate distribution chain illegal." H. R. Rep. No. 91-1444, p. 3. Although this language is ambiguous, the most sensible interpretation is that the penalty to be imposed for a violation was intended to turn on whether the "transaction" falls within or without legitimate channels. All persons who engage in legitimate transactions must be registered and are subject to penalties under 842 and 843 for "[m]ore or less technical violations." H. R. Rep. No. 91-1444, p. 10. But "severe criminal penalties" were imposed on those, like respondent, who sold drugs, not for legitimate purposes, but "primarily for the profits to be derived therefrom." Ibid.

C

Congress was particularly concerned with the diversion of drugs from legitimate channels to illegitimate channels. Id., at 6; S. Rep. No. 91-613, p. 4; 116 Cong. Rec. 996 (1970) (remarks of Sen. Dodd). It was aware that registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic. See id., at 1663 (remarks of Sen. Hruska); id., at 998 (remarks of Sen. Griffin).

Recognizing this concern the Court of Appeals suggested that Dr. Moore could be prosecuted under 842 [423 U.S. 122, 136] (a) (1) for having violated the provisions of 829 with respect to the issuing of

prescriptions. 12 Whether Dr. Moore could have been so prosecuted is not before the [423 U.S. 122, 137] Court. 13 We note, however, that the penalties for such a violation could hardly have been deemed by Congress to be an appropriate sanction for drug trafficking by a registered physician. Indeed, the penalty for conviction under 842 would be significantly lighter than, for example, that applicable to a registrant convicted under 843 for using a suspended registration number. 14 Moreover, a physician who wished to traffic in drugs without threat of criminal prosecution could, if violation of 829 were the sole basis for prosecution, simply dispense drugs directly without the formality of issuing a prescription. Direct dispensing is exempt from 829 and thus is not reached by any subsection of 842 or [423 U.S. 122, 138] 843 so long as the technical requirements are complied with.

But we think it immaterial whether Dr. Moore also could have been prosecuted for his violation of statutory provisions relating to dispensing procedures. There is nothing in the statutory scheme or the legislative history that justifies a conclusion that a registrant who may be prosecuted for the relatively minor offense of violating 829 is thereby exempted from prosecution under 841 for the significantly greater offense of acting as a drug "pusher." 15

III

Respondent argues that even if Congress did not intend to exempt registrants from all prosecutions under 841, he cannot be prosecuted under that section because the specific conduct for which he was prosecuted was "authorized by [the] subchapter" and thus falls within the express exemption of the section.

The trial judge assumed that a physician's activities are authorized only if they are within the usual course of professional practice. He instructed the jury that it had to find

> "beyond a reasonable doubt that a physician, who knowingly or intentionally, did dispense or distribute [423 U.S. 122, 139] [methadone] by prescription, did so other than in good faith for detoxification in the usual course of a professional practice and in accordance with a standard of medical practice generally recognized and accepted in the United States." App. 123.

The Court of Appeals did not address this argument because it concluded that registrants could not be prosecuted under 841 under any circumstances. But it suggested that if a registrant could be reached under 841 he could not be prosecuted merely because his activities fall outside the "usual course of practice." 164 App. D.C., at 322 n. 11, 505 F.2d, at 429 n. 11.

Under the Harrison Act physicians who departed from the usual course of medical practice were subject to the same penalties as street pushers with no claim to legitimacy. Section 2 of that Act required all persons who sold or prescribed certain drugs to register and to deliver drugs only to persons with federal order forms. The latter requirement did not apply to "the dispensing or distribution of any of the aforesaid drugs to a patient by a physician . . . registered under this Act in the course of his professional practice only." 38 Stat. 786. As noted above, Congress intended the CSA to strengthen rather than to weaken the prior drug laws. There is no indication that Congress intended to eliminate the existing limitation on the exemption given to doctors. 16 The difficulty [423 U.S. 122, 140] arises because the CSA, unlike the Harrison Act, does not spell out this limitation in unambiguous terms.

Instead of expressly removing from the protection of the Act those physicians who operate beyond the bounds of professional practice, the CSA uses the concept of "registration." Section 822 (b) defines the scope of authorization under the Act in circular terms: "Persons registered . . . under this subchapter . . . are authorized [to dispense controlled substances] . . . to the extent authorized by their registration and in conformity with the other provisions of this subchapter." But the scheme of the statute, viewed against the background of the legislative history, reveals an intent to limit a registered physician's dispensing authority to the course of his "professional practice."

Registration of physicians and other practitioners 17 is mandatory if the applicant is authorized to dispense drugs or conduct research under the law of the State in which he practices. 18 823 (f). In the case of a physician [423 U.S. 122, 141] this scheme contemplates that he is authorized by the State to practice medicine and to dispense drugs in connection with his professional practice. 19 The federal registration, which follows automatically, extends no further. It authorizes transactions within "the legitimate distribution chain" and makes all others illegal. H. R. Rep. No. 91-1444, p. 3. Implicit in the registration of a physician is the understanding that he is authorized only to act "as a physician."

This is made explicit in 802 (20), which provides that "practitioner" means one who is "registered . . . by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research." This section defines the term "practitioner" for purposes of the Act. It also describes the type of registration contemplated by the Act. That registration is limited to the dispensing and use of drugs "in the course of professional practice or research."

Other provisions throughout the Act reflect the intent [423 U.S. 122, 142] of Congress to confine authorized medical practice within accepted limits. Section 812 (b) (2) includes in its definition of Schedule II drugs a requirement that "[t]he drug [have] a currently accepted medical use with severe restrictions." Registration under the CSA to dispense or to conduct research with Schedule I drugs, which are defined as having "no currently accepted medical use in treatment in the United States," 812 (b) (1) (B), does not follow automatically from state registration as it does with respect to drugs in Schedules II through V, all of which have some accepted medical use. 823 (f). The record and reporting requirements of 827 are made inapplicable with respect to narcotic drugs in Schedules II through V when they are prescribed or administered "by a practitioner in the lawful course of his professional practice." 827 (c) (1) (A). Section 828 (a) prohibits the distribution of Schedule I and II drugs unless pursuant to specified order forms; 828 (e) makes it unlawful for "any person" to obtain drugs with these order forms "for any purpose other than their use, distribution, dispensing, or administration in the conduct of a lawful business in such substances or in the course of his professional practice or research." Section 844 (a) prohibits possession of controlled substances unless the drug was obtained "from a practitioner, while acting in the course of his professional practice, or except as otherwise authorized . . . ." See also 885 (a) (2).

The evidence presented at trial was sufficient for the jury to find that respondent's conduct exceeded the bounds of "professional practice." 20 As detailed above, he gave inadequate physical examinations or none at all. [423 U.S. 122, 143] He ignored the results of the tests he did make. He did not give methadone at the clinic and took no precautions against its misuse and diversion. He did not regulate the dosage at all, prescribing as much and as frequently as the patient demanded. He did not charge for medical services rendered, but graduated his fee according to the number of tablets desired. In practical effect, he acted as a large-scale "pusher" - not as a physician.

IV

Respondent further contended at trial that he was experimenting with a new "blockade" theory of detoxification. The jury did not believe him. Congress understandably was concerned that the drug laws not impede legitimate research and that physicians be allowed reasonable discretion in treating patients and testing new theories. But respondent's interpretation of the Act would go far beyond authorizing legitimate research and experimentation by physicians. It would even compel exemption from the provisions of 841 of all "registrants," including manufacturers, wholesalers, and pharmacists - in addition to physicians.

In enacting the Comprehensive Drug Abuse Prevention and Control Act of 1970, 84 Stat. 1236, Title II of which is the CSA, Congress faced the problem directly. Because of the potential for abuse it decided

that some limits on free experimentation with drugs were necessary. But it was also aware of the concern expressed by the Prettyman Commission:

> "[A] controversy has existed for fifty years over the extent to which narcotic drugs may be administered to an addict solely because he is an addict.
>
> . . . . .
>
> "The practicing physician has . . . been confused as to when he may prescribe narcotic drugs for an [423 U.S. 122, 144] addict. Out of a fear of prosecution many physicians refuse to use narcotics in the treatment of addicts except occasionally in a withdrawal regimen lasting no longer than a few weeks. In most instances they shun addicts as patients." 21

Congress' solution to this problem is found in 4 of Title I of the 1970 Act, 42 U.S.C. 257a. That section requires the Secretary of Health, Education, and Welfare, after consultation with the Attorney General and national addict treatment organizations, to "determine the appropriate methods of professional practice in the medical treatment of . . . narcotic addiction . . . ." It was designed "to clarify for the medical profession . . . the extent to which they may safely go in treating narcotic addicts as patients." H. R. Rep. No. 91-1444, p. 14. Congress pointed out that "criminal prosecutions" in the past had turned on the opinions of federal prosecutors. Under the new Act, "[t]hose physicians who comply with the recommendations made by the Secretary will no longer jeopardize their professional careers . . . ." Id., at 15. The negative implication is that physicians who go beyond approved practice remain subject to serious criminal penalties.

In the case of methadone treatment the limits of approved practice are particularly clear. As Dr. Moore admitted at trial, 22 he was authorized only to dispense methadone for detoxification purposes. His authorization by the FDA to engage in a methadone maintenance program had been revoked. Nor was respondent unfamiliar with the procedures for conducting a legitimate detoxification program. Charges arising [423 U.S. 122, 145] out of his 1969 treatment program, which involved a combination of "long term" and "short term" detoxification, were dropped after he testified before a grand jury and agreed to abide by certain medical procedures in future methadone programs. These included obtaining a medical history of each patient, conducting a reasonably thorough physical examination, abiding by the results of urine tests, recording times and amounts of dosages, and either administering the methadone in his office or prescribing no more than a daily dosage. 23 At trial respondent admitted that he had failed to follow these procedures. 24

V

Respondent argues finally that the statute is sufficiently ambiguous that it must be construed in his favor despite the clear intent of the Congress. It is true that "when choice has to be made between two readings of what conduct Congress has made a crime, it is appropriate, before we choose the harsher alternative, to require that Congress should have spoken in language that is clear and definite." United States v. Universal C. I. T. Credit Corp., 344 U.S. 218, 221-222 (1952). In this case, however, the principle set forth in United States v. Brown, 333 U.S. 18, 25-26 (1948), is appropriately followed:

> "The canon in favor of strict construction [of criminal statutes] is not an inexorable command to override common sense and evident statutory purpose. . . . Nor does it demand that a statute be given the 'narrowest meaning'; it is satisfied if the words are given their fair meaning in accord with the manifest intent of the lawmakers." [423 U.S. 122, 146]

The judgment of the Court of Appeals is reversed. Because of its disposition of the case, that court did not reach the question whether respondent could be sentenced under 21 U.S.C. 845, which provides a higher penalty for distribution of controlled substances to persons under 21 years of age. We remand for

the sole purpose of considering respondent's claim that he was improperly sentenced under that section.

So ordered.

Footnotes

[Footnote 1] A substance listed in Schedule II has "a high potential for abuse," "a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions," and is a drug the abuse of which "may lead to severe psychological or physical dependence." 21 U.S.C. 812 (b) (2). Methadone is listed as a Schedule II drug in 812 (c), Schedule II (b) (11).

[Footnote 2] In addition, Dr. Moore's license to practice medicine was revoked pursuant to D.C. Code Ann. 2-131 (1973), which authorizes revocation upon the conviction of "any felony." An appeal from the conviction acts "as a supersedeas to the judgment . . . revoking his license . . . ."

[Footnote 3] One patient testified that he was taking approximately two to three pills per day when he started visiting Dr. Moore. By the end of his visits he was taking 30 to 35 pills a day. App. 43. Another patient increased his intake from five to 10 pills a day to almost 70. Id., at 53-54. A third addict, relying on Dr. Moore for drugs, increased his intake from seven pills a day to over 100. Tr. 310.

[Footnote 4] Section 841 (a) provides, in full: "Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally - "(1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance; or "(2) to create, distribute, or dispense, or possess with intent to distribute or dispense, a counterfeit substance." "Dispense" is defined in 802 (10) to mean "to deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance . . . ." Section 802 (11) defines "distribute" to mean "to deliver (other than by administering or dispensing) a controlled substance." "Administer" refers to "the direct application of a controlled substance to the body of a patient . . . ." 802 (2).

[Footnote 5] Section 842 in relevant part provides: "(a) Unlawful acts. "It shall be unlawful for any person - "(1) who is subject to the requirements of part C to distribute or dispense a controlled substance in violation of section 829 of this title; "(2) who is a registrant to distribute or dispense a controlled substance not authorized by his registration to another registrant or other authorized person or to manufacture a controlled substance not authorized by his registration; "(3) who is a registrant to distribute a controlled substance in violation of section 825 of this title; "(4) to remove, alter, or obliterate a symbol or label required by section 825 of this title; "(5) to refuse or fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under this subchapter or subchapter II of this chapter; "(6) to refuse any entry into any premises or inspection authorized by this subchapter or subchapter II of this chapter; "(7) to remove, break, injure, or deface a seal placed upon controlled substances pursuant to section 824 (f) or 881 of this title or to remove or dispose of substances so placed under seal; or "(8) to use, to his own advantage, or to reveal, other than to duly authorized officers or employees of the United States, or to the courts when relevant in any judicial proceeding under this subchapter or subchapter II of this chapter, any information acquired in the course of an inspection authorized by this subchapter concerning any method or process which as a trade secret is entitled to protection. "(b) Manufacture. "It shall be unlawful for any person who is a registrant to manufacture a controlled substance in Schedule I or II which is - "(1) not expressly authorized by his registration and by a quota assigned to him pursuant to section 826 of this title; or "(2) in excess of a quota assigned to him pursuant to section 826 of this title." [423 U.S. 122, 129] Section 843 provides: "(a) Unlawful acts. "It shall be unlawful for any person knowingly or intentionally - "(1) who is a registrant to distribute a controlled substance classified in schedule I or II, in the course of his legitimate business, except pursuant to an order or an order form as

required by section 828 of this title; "(2) to use in the course of the manufacture or distribution of a controlled substance a registration number which is fictitious, revoked, suspended, or issued to another person; "(3) to acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge; "(4) to furnish false or fraudulent material information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed under this subchapter or subchapter II of this chapter; or "(5) to make, distribute, or possess any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit substance. "(b) Communication facility. "It shall be unlawful for any person knowingly or intentionally to use any communication facility in committing or in causing or facilitating the commission of any act or acts constituting a felony under any provision of this subchapter or subchapter II of this chapter. Each separate use of a communication facility shall be a separate offense under this subsection. For purposes of this subsection, the term `communication facility' means any and all public and private instrumentalities used or useful in the transmission of writing, signs, signals, pictures, or sounds of all kinds and includes mail, telephone, wire, radio, and all other means of communication."

[Footnote 6] Violations of 841, under which respondent was convicted, carry sentences of up to 15 years, fines as high as $25,000, [423 U.S. 122, 130] or both. 841 (b). Knowing violators of 842 are subject at most to imprisonment for one year, a fine of $25,000, or both. There also may be a civil penalty of $25,000 for violation of 842. 842 (c). The penalties for violation of 843 are imprisonment for not more than four years, a fine of not more than $30,000, or both. 843 (c). All three sections impose higher penalties for violations after the first conviction.

[Footnote 7] The decision below stands alone. At the time it was issued it conflicted with the rulings of four other Circuits. Courts of Appeals for the First, Fifth, and Tenth Circuits had held squarely that physicians may be prosecuted under 841. See United States v. Badia, 490 F.2d 296 (CA1 1973); United States v. Collier, 478 F.2d 268 (CA5 1973); United States v. Leigh, 487 F.2d 206 (CA5 1973); United States v. Bartee, 479 F.2d 484 (CA10 1973); United States v. Jobe, 487 F.2d 268 (CA10 1973). The Ninth Circuit also had affirmed the conviction of a physician under 841 (a) (1). United States v. Larson, 507 F.2d 385 (1974). Since the ruling in this case, two other decisions have considered the issue and expressly rejected the analysis of the Court of Appeals for the District of Columbia Circuit. See United States v. Rosenberg, 515 F.2d 190 (CA9 1975); United States v. Green, 511 F.2d 1062 (CA7 1975). The Sixth Circuit has implicitly agreed. It reversed the conviction of a physician and remanded the case for a new trial because the trial court had failed to instruct the jury that physicians are exempt from prosecution under 841 (a) (1) when they dispense or prescribe controlled substances in good faith to patients in the regular course of [423 U.S. 122, 131] professional practice. United States v. Carroll, 518 F.2d 187 (1975).

[Footnote 8] To this end controlled substances were classified in five categories according to their potential for abuse, their promise for treatment, and their psychological and physical effects. 812.

[Footnote 9] Section 822 (b) was added by the House Committee on Interstate and Foreign Commerce. No comparable section was in the Act when it passed the Senate on January 28, 1970.

[Footnote 10] This represents a commonsense recognition by Congress that only a registrant could, for example, distribute drugs "not authorized by his registration," 842 (a) (2), or manufacture substances "not expressly authorized by his registration" or "in excess of [his] [423 U.S. 122, 134] quota." 842 (h) (1), (2). Nor would there be any reason to apply to nonregistrants the penalties for distributing drugs without complying with the labeling and order-form requirements of the Act, 842 (a) (3), 843 (a) (1), for nonregistrants are barred from making any distributions whatsoever.

[Footnote 11] Another subsection which can be sensibly interpreted only if it reaches nonregistrants is

842 (a) (1), which is limited to "any person - who is subject to the requirements of part C." Part C of the Act, 821-829, covers the provisions for registration and applies to "[e]very person who manufactures, distributes, or dispenses any controlled substance or who proposes" to do so. 822 (a). Presumably, 842 (a) (1) is so phrased in order to reach those who should have registered but failed to do so.

[Footnote 12] Section 829 provides, in part: "(a) Schedule II substances. "Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed without the written prescription of a practitioner, except that in emergency situations, as prescribed by the Secretary by regulation after consultation with the Attorney General, such drug may be dispensed upon oral prescription in accordance with section 353 (b) of this title. Prescriptions shall be retained in conformity with the requirements of section 827 of this title. No prescription for a controlled substance in schedule II may be refilled. "(b) Schedule III and IV substances. "Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule III or IV, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed without a written or oral prescription in conformity with section 353 (b) of this title. Such prescriptions may not be filled or refilled more than six months after the date thereof or be refilled more than five times after the date of the prescription unless renewed by the practitioner. "(c) Schedule V substances. "No controlled substance in schedule V which is a drug may be distributed or dispensed other than for a medical purpose." The Attorney General's regulations enacted pursuant to 829 required: "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of [423 U.S. 122, 137] section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances." 21 CFR 306.04 (a) (1973) (redesignated as 21 CFR 1306.04 (a) (1975)). The court below suggested that a violation of the "medical purpose" requirement of 306.04 (a) makes a prescription something other than the "written prescription" required by 829. The dissent, which agreed that Dr. Moore could be prosecuted under 842 (a) (1), did not rely on the regulations. It found inherent in the statutory term "prescription" a requirement that the order be issued for a valid medical purpose.

[Footnote 13] On its face 829 addresses only the form that a prescription must take. A written prescription is required for Schedule II substances. 829 (a). Either a written or an oral prescription is adequate for drugs in Schedules III and IV. 829 (b). The only limitation on the distribution or dispensing of Schedule V drugs is that it be "for a medical purpose." 829 (c). The medical purpose requirement explicit in subsection (c) could be implicit in subsections (a) and (b). Regulation 306.04 makes it explicit. But 829 by its terms does not limit the authority of a practitioner.

[Footnote 14] In addition, a doctor who dispenses a controlled substance not authorized by his registration to another registrant is also covered by 842 and would thus be punished as severely as a doctor who sold drugs solely for financial profit to nonregistrants. 842 (a) (2).

[Footnote 15] Respondent argues that the proper sanction for trafficking physicians is not criminal prosecution, but deregistration or refusal to reregister. But, under respondent's analysis, at the time he was convicted neither penalty could be imposed as a sanction for the conduct in which he engaged. Registration was mandatory for practitioners with state licenses, 823 (f), and could only be suspended or revoked if the state license was revoked or suspended, if the practitioner had "materially falsified" an application under the Act, or if he had been convicted of a drug-related felony. 824 (a). Conviction for a misdemeanor under 842 would be insufficient to support revocation.

[Footnote 16] The Narcotic Addict Treatment Act of 1974 (NATA), 88 Stat. 124, 21 U.S.C. 802, 823, 824 (1970 ed., Supp. IV), modified the registration and revocation procedures provided in the CSA in order to facilitate "more expeditious" criminal prosecutions by making revocation easier. There was no indication that Congress thought that trafficking doctors could escape felony prosecution altogether under pre-NATA law. Rather, it sought to "cure the present difficulty in such prosecutions because of the intricate and nearly impossible burden of establishing what is beyond `the course of professional practice' for [423 U.S. 122, 140] criminal law purposes when such a practitioner speciously claims that the practices in question were ethical and humanitarian in nature." S. Rep. No. 93-192, p. 14 (1973). Dr. Moore's conviction was cited to illustrate that successful criminal actions could be brought only "in the most aggravated of circumstances . . . after prolonged effort to make undercover penetrations." Id., at 13.

[Footnote 17] "Practitioner" means "a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research." 802 (20).

[Footnote 18] Under 823, registration of manufacturers and nonpractitioner distributors (such as suppliers) is discretionary with the Attorney General. He first must make a finding that registration is consistent (in the case of manufacturers of Schedule I and II drugs) or not inconsistent (in the case of manufacturers of Schedule III-V [423 U.S. 122, 141] drugs and all distributors) with the public interest. In evaluating the public interest the Attorney General is to consider, for example, "maintenance of effective controls against diversion," compliance with applicable state and local law, prior conviction record in drug-related charges, past experience, and (in the case of manufacturers) promotion of technical advances in manufacturing and the development of new substances. Practitioners and pharmacies are automatically entitled to registration to handle drugs in Schedules II-V "if they are authorized to dispense . . . under the law of the State in which they practice." 823 (f).

[Footnote 19] The House Report described the rationale behind 823 (f) as follows: "Practitioners . . . engaged in the distribution chain would be required to be registered, but registration would be as a matter of right where the individual or firm is engaged in activities involving these drugs which are authorized or permitted under State law . . . ." H. R. Rep. No. 91-1444, p. 23 (1970) (emphasis added).

[Footnote 20] The jury was instructed that Dr. Moore could not be convicted if he merely made "an honest effort" to prescribe for detoxification in compliance with an accepted standard of medical practice. App. 124.

[Footnote 21] Report of the President's Advisory Commission on Narcotic and Drug Abuse 56-57 (1963), quoted in H. R. Rep. No. 91-1444, pp. 14-15.

[Footnote 22] App. 101.

[Footnote 23] Id., at 97-100, 116, 136-138.

[Footnote 24] Id., at 97-100. [423 U.S. 122, 147]

DEA Internet Policy

business on June 13, 2001. All submissions should be addressed to the Secretary, United States International Trade Commission, 500 E Street SW., Washington, DC 20436.

Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000.

LIST OF SUBJECTS: Chile, tariffs, and imports.

By order of the Commission.
Issued: April 24, 2001.

Donna R. Koehnke,
Secretary.

[FR Doc. 01–10527 Filed 4–26–01; 8:45 am]
BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[DEA–191N]

Dispensing and Purchasing Controlled Substances over the Internet

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Guidance.

SUMMARY: This notice is intended to provide guidance to prescribers, pharmacists, law enforcement authorities, regulatory authorities, and the public concerning the application of current laws and regulations as they relate to the use of the Internet for dispensing, purchasing, or importing controlled substances. This guidance document explains when controlled substances can be legally purchased from U.S.-based Internet sites. This notice clarifies that consumers must have valid prescriptions to obtain controlled substances legally and that consumers cannot legally purchase controlled substances from foreign supplier Internet sites and have them shipped to the U.S, unless the consumers are registered with DEA as controlled substances importers and are in compliance with all DEA requirements.

FOR FURTHER INFORMATION CONTACT: Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537. Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION:

Why is This Notice Necessary?

With the advent of Internet pharmacies, DEA registrants and the public have asked how these Internet pharmacies fit into the requirements that currently exist for the prescribing and dispensing of controlled substances. DEA is issuing this notice to provide guidance to prescribers, pharmacists, law enforcement authorities, regulatory authorities, and the public about the application of current laws and regulations to the use of the Internet for prescribing, dispensing, purchasing, or importing controlled substances.

This document is in the format of questions and answers. The first section provides the context for this notice. The next two sections address issues that apply to DEA registrants and consumers.

General Questions

What are Controlled Substances?

Most drugs that require a prescription from a doctor are not controlled substances. The Controlled Substances Act and its implementing regulations, however, assign certain substances to one of five "schedules." These substances are placed in a schedule based on their potential for abuse, which may lead to physical or psychological dependency. Schedule I substances have no accepted medical use for treatment in the United States and are not available by prescription. Schedule II through V substances have accepted medical use and varying potentials for abuse and dependency. Practitioners (*e.g.*, doctors, dentists, veterinarians, physician assistants, advance practice nurses) who are licensed by a State and registered with DEA may prescribe these substances. Controlled substances include narcotics (pain relievers), stimulants, depressants, hallucinogens, and anabolic steroids. A complete list of controlled substances can be found in Title 21 of the Code of Federal Regulations (CFR) part 1308. Examples of controlled substances are shown below.

Schedule	Example of controlled substances
Schedule I	Heroin, marijuana, mescaline, methcathinone,
Schedule II	Amphetamine, codeine, fentanyl, Hydromorphone, meperidine, methadone, Methylphenidate (Ritalin), morphine, oxycodone, pentobarbital, phencyclidine (PCP), secobarbital
Schedule III	Anabolic steroids, phendimetrazine, and products that contain small quantities of certain schedule II controlled substances, such as codeine, in combination with noncontrolled ingredients, such as aspirin.
Schedule IV	Alprazolam (Xanax), chlordiazepoxide (Librium), diazepam (Valium), lorazepam (Ativan), phenobarbital, phentermine
Schedule V	Buprenorphine and many cough Preparations that contain a limited amount of codeine

What are the Basic Requirements for Prescribing, Dispensing, and Importing Controlled Substances?

Only practitioners acting in the usual course of their professional practice may prescribe controlled substances. These practitioners must be registered with DEA and licensed to prescribe controlled substances by the State(s) in which they operate. Pharmacies filling prescriptions for controlled substances must also be registered with DEA and licensed to dispense controlled substances by the State(s) in which they operate. A prescription not issued in the usual course of professional practice or not for legitimate and authorized research is not considered valid. Both the practitioner and the pharmacy have a responsibility to ensure that only legitimate prescriptions are written and filled.

Pharmacists must receive written and manually signed prescriptions for Schedule II substances. They may receive oral or faxed prescriptions for Schedules III–V substances provided they confirm the legitimacy of the prescription and the practitioner. Prescriptions for Schedule II substances may not be refilled. Prescriptions for Schedules III–V controlled substances may be refilled five times, but no prescription may be filled or refilled more than six months after the date on which the prescription was issued. Only those people who are registered with DEA as importers and who are in compliance with DEA requirements may have controlled substances shipped into the customs territory or jurisdiction of the U.S. from a foreign country.

DEA regulations covering prescriptions can be found in Title 21 of the Code of Federal Regulations, part 1306; rules on importation are found in 21 CFR 1312.

Why are Internet Sales an Issue?

The Internet is primarily a communications tool that can be used to facilitate any type of business. On-line pharmacies are currently providing access to a full range of pharmaceuticals, including prescription drugs and controlled substances. Many people view the Internet as changing the way in which business is conducted. For controlled substances, however, the Controlled Substances Act and DEA's regulations continue to determine when and how these substances may be obtained. Internet sales must be in accordance with these requirements.

DEA rules affect how controlled substances may be ordered from an Internet pharmacy and the conditions under which such orders are legal. DEA is currently working on a revision to its regulations that will define the conditions under which prescribers may electronically sign and transmit to any pharmacy (retail, mail order, or Internet) prescriptions for controlled substances. Until these revisions are complete, however, use of the Internet for dispensing controlled substances is governed by existing DEA rules, described above.

DEA is issuing this notice to answer questions that legitimate pharmacies and practitioners have about using the Internet as part of their business. DEA is also aware that some Internet sites are engaged in the illegal sale of controlled substances. Consumers may be illegally purchasing controlled substances from these Internet sites without realizing that they are committing a crime. This notice provides information for consumers to help them understand when they may legally purchase controlled substances.

DEA Registrant Questions About Internet Pharmacies

Must my Internet Pharmacy be Registered with DEA?

The actual physical location of the pharmacy which purchases, stores and dispenses controlled substances pursuant to prescription orders processed by the Internet site must be registered with DEA. The web site itself would not require a separate registration unless it is the same physical location, since the web site does not store or dispense controlled substances. For example, some Internet pharmacies maintain a central pharmacy warehouse site and offices where prescriptions are verified and substances shipped; this location must be registered with DEA as a retail pharmacy. Other Internet sites allow patients to pick up their prescriptions for controlled substances from a local pharmacy; these local pharmacies must be registered with DEA. In this case, the Internet "pharmacy" has no obligations under DEA regulations because the responsibility for assuring compliance with DEA regulations rests with the actual pharmacy where the controlled substances are dispensed.

Your pharmacy must have a license from the State in which the controlled substances are stored and dispensed and, in most instances, from any state in which you plan to conduct business with customers. You should also be aware that many States require licenses for the web site itself since these sites often provide services like patient counseling.

Does the Label on a Prescription I Fill Indicate the Internet Pharmacy or the Registered Location that Filled the Prescription?

The label must list the registered location that dispensed the controlled substance.

Does Being an Internet Pharmacy Change my Responsibilities Under DEA Regulations?

No, you are still authorized to sell controlled substances only when there is a valid prescription from a DEA-registered practitioner who issued the prescription in the usual course of his or her professional practice.

Is it Possible for my Internet Pharmacy to Fill Prescriptions for Schedule II Substances?

You may fill valid prescriptions for Schedule II substances if the patient or prescriber provides you with the signed original prescriptions prior to dispensing. Practically, it is unlikely that most patients will want to wait the time required for such a transaction.

Is it Possible for my Internet Pharmacy to Fill Prescriptions for Schedule III–V Substances?

You may receive an original signed prescription or a facsimile of the original signed prescription, or an oral prescription, where allowed, which you verify and immediately reduce to writing. You have the responsibility to ensure the legitimacy of the prescription and the prescriber. At this time, DEA does not permit a prescription received via the Internet to be filled. If you receive prescription information transmitted via the Internet, you must contact the prescriber via telephone and receive an oral prescription for the controlled substance, including the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the name, address and registration number of the practitioner (21 CFR 1306.05(a)). You must immediately reduce this oral prescription to writing (21 CFR 1306.21(a)).

Does DEA Intend to Allow Electronic Transmission of Prescriptions in the Future?

DEA is currently engaged in a project to determine the requirements for secure electronic transmission of all controlled substance prescriptions between the practitioner and the pharmacy. When completed, these requirements will automatically certify the authenticity of the prescriber, protect the content of the prescription from alteration, and bind the digital signature on the prescription to the actual prescriber and no one else. These requirements will be subject to rulemaking, and you will have an opportunity to comment on them before they are finalized. You can find more information on this project on the DEA web site at http://www.deadiversion.usdoj.gov/ecomm/index.html.

Can Patients Request a Refill of a Controlled Substance Prescription From my Pharmacy by Sending me an email Instead of Calling me on the Telephone?

Yes, the Internet can be used to facilitate communication between you and your patient when your patient is requesting a permissible refill of an existing Schedule III–V controlled substance prescription.

Some Internet Pharmacies have Doctors who Prescribe Substances Based on an on-line Questionnaire. Is this Legal?

Federal law requires that "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice" (21 CFR 1306.04(a)). Every state separately imposes the same requirement under its laws. Under Federal and state law, for a doctor to be acting in the usual course of professional practice, there must be a bona fide doctor/patient relationship.

For purposes of state law, many state authorities, with the endorsement of medical societies, consider the existence of the following four elements as an indication that a legitimate doctor/patient relationship has been established:

- A patient has a medical complaint;
- A medical history has been taken;
- A physical examination has been performed; and

• Some logical connection exists between the medical complaint, the medical history, the physical examination, and the drug prescribed.

Completing a questionnaire that is then reviewed by a doctor hired by the Internet pharmacy could not be considered the basis for a doctor/patient relationship. A consumer can more easily provide false information in a questionnaire than in a face-to-face meeting with a doctor. It is illegal to receive a prescription for a controlled substance without the establishment of a legitimate doctor/patient relationship, and it is unlikely for such a relationship to be formed through Internet correspondence alone. However, as discussed later in this document, this circumstance is not intended to limit the ability of practitioners to engage in telemedicine. For purposes of this guidance document, telemedicine refers to the provision of health care using telecommunication networks to transmit and receive information including voice communications, images, and patient records.

Some sites recommend to the patient that they not take a new drug before they have a complete physical performed by a doctor. These sites then ask the patient to waive the requirement for a physical and to agree to have a physical before taking the drug they purchase via the Internet. An after-the-fact physical does not take the place of establishing a doctor/patient relationship. The physical exam should take place before the prescription is written. These types of activities by Internet pharmacies can subject the operators of the Internet site and any pharmacies or doctors who participate in the activity to criminal, civil, or administrative actions. For DEA registrants administrative action may include the loss of their DEA registration. Additionally, providing false material information to obtain controlled substances could be considered obtaining a controlled substance by fraud and deceit, which is subject to Federal and State penalties.

I am a Practitioner who is Considering Starting an Internet Practice. Can I use the Internet to Facilitate the Prescribing of Controlled Substances?

You may use the Internet to provide information and to communicate with the patient, but it cannot be the sole basis for authorizing prescriptions. If a doctor/patient relationship exists, you can use the Internet to communicate with patients. Where a doctor/patient relationship exists, you may use the Internet to receive requests for treatment. DEA cautions, however, that such requests for treatment should be logical based on your knowledge of the patient's medical history and the medical complaint. You may also use the Internet to receive requests for refills of prescriptions from patients.

I am a Physician. Does the need for a Physical Exam Mean that I Cannot Engage in Telemedicine and Prescribe Controlled Substances?

No; DEA does not intend to limit the ability of doctors to engage in telemedicine. If the patient cannot travel to your office, but you supervise an exam given by a nurse or other professional, you can then prescribe the needed medications based on the results, to the extent that State law allows. In this case, your decision on the appropriateness of the medication is based on facts (symptoms, blood pressure, etc.) that have been verified by a qualified third party and observed by you electronically.

I have Read in the Controlled Substances Act (CSA) that it is a Violation of the law to use a Communications Facility to Facilitate the Illegal sale of a Controlled Substance. Does this Apply to the use of the Internet to Obtain Pharmaceutical Controlled Substances?

Yes, Title 21, United States Code, section 843(b) defines a communication facility as "any and all public and private instrumentalities used or useful in the transmission of writing, signs, signals, pictures or sounds of all kinds and includes mail, telephone, wire, radio, and all other means of communication." Anyone who uses the Internet to facilitate the illegal sale of a controlled substance would be in violation of 21 U.S.C. 843(b), which is punishable by a term of imprisonment of not more than four years and a fine of not more than $30,000. This provision could apply to owners of Internet sites, prescribers, pharmacists, and patients.

Questions for Consumers

Are Internet Pharmacy Sites Legitimate?

Many Internet pharmacy sites are legitimate. These Internet pharmacy sites may vary in the services they provide, but they may fill a prescription for a controlled substance which was issued to you by an authorized practitioner for a legitimate medical purpose. They should confirm the legitimacy of the prescription for a Schedule III–V controlled substance before filling it by contacting the prescriber. They are not authorized to fill a prescription for a Schedule II controlled substance unless they have first received the original signed prescription.

Some Internet sites for pharmacies advertise local pharmacies and usually list the name, address, and telephone number of the local pharmacy closest to you. Many of these sites provide a great deal of information concerning specific diseases or medical conditions, and drug information. Many Internet sites operated by local pharmacies or mail order pharmacies serve as a communication link so that you can request refills of prescriptions, check the status of your prescription, or ask the pharmacist a question. These are appropriate uses of the Internet by pharmacies.

Some sites simply provide information about specific drugs and medical conditions. After obtaining some general information from you, this type of "Internet Pharmacy" will refer you to a specific local pharmacy or a mail order pharmacy to have the prescription that you obtained from your physician filled. These are appropriate uses of the Internet by pharmacies.

Are There Internet Pharmacy Sites That are Not Legitimate?

Some Internet pharmacy sites do not require that you have a prescription from your doctor. These "Internet Pharmacies" require the customer to complete a medical questionnaire. This type of site advises that the information will be reviewed by a doctor, and the drug will be prescribed and sent to you, if appropriate. The medical questionnaire often has most of the questions set so that if the default answers are not changed, the questions are answered in an appropriate manner to obtain the desired drug. Questionnaire sites often require that the customer waive certain rights. This type of pharmacy usually does not name the doctor who will be reviewing the medical questionnaire or provide any information about the qualifications of the doctor. These sites operate in a manner that is not consistent with state laws regarding standards of medical practice and may be engaging in illegal sales of controlled substances (see discussion above).

Some Internet Pharmacy sites are operating in a foreign country and often do not require any prescription before sending controlled substances to you. These sites often advise that there have been changes to the U.S. law that authorize the customer to import a controlled substance into the United States without benefit of a prescription. These types of sites may be engaging in

illegal sales of controlled substances (see discussion below).

Is it Legal to Buy Controlled Substances From Foreign Internet Sites and Have Them Shipped to the U.S.?

No, having controlled substances shipped to the U.S. is illegal unless you are registered with DEA as an importer and you are in compliance with 21 U.S.C. 952, 953, and 954 and 21 CFR part 1312. Some foreign Internet sites claim they can legally sell these controlled substances; other sites, knowing that such shipments are illegal, advise consumers of ways to avoid having the packages seized by U.S. Customs. The Controlled Substances Act prohibits any person from importing into the customs territory of the U.S. any controlled substance or List I chemical (21 U.S.C. 971 and 21 CFR part 1313) unless that person maintains a valid, current authorization to import such substances or chemicals (21 U.S.C. 957(a)). DEA regulations further state:

"No person shall import or cause to be imported any controlled substance * * * unless and until such person is properly registered under the Act (or exempt from registration) and the Administrator has issued him a permit to do so pursuant to § 1312.13. * * *" (21 CFR 1312.11(a))

Illegal importation of controlled substances is a felony that may result in imprisonment and fines (21 U.S.C. 960).

The CSA Provides a Personal Use Exemption for Controlled Substances Purchased Abroad. Does the Exemption Apply to Controlled Substances Bought from a Foreign Internet Site?

The Controlled Substances Act and DEA regulations allow you a personal use exemption to bring a limited quantity of controlled substances into the U.S. for your use only when you bring the controlled substances across the U.S. border in your possession (21 U.S.C. 956, 21 CFR 1301.26). It does not apply to controlled substances being shipped into the U.S. Purchasing controlled substances on the Internet and having them shipped to you in the U.S. is not permitted by the personal use exemption. Such purchases and shipments would be considered "imports" of the controlled substance even if the substance is for your personal use. Unless you are registered as an importer and in compliance with the requirements, such shipments are illegal and subject to seizure.

Does it Make a Difference if I Have a Prescription from a U.S. Doctor for Controlled Substances That I Buy From a Foreign Internet Site?

No, the law remains the same. Unless you are registered with DEA as an importer and are in compliance with DEA's requirements, you may not have controlled substances shipped to you in the U.S. from another country.

What are the Things to Consider in Selecting an Internet Pharmacy?

An "Internet Pharmacy" site should provide a physical address for the pharmacy, in addition to the Internet address, and a telephone number for the pharmacy.

Some indicators that the "Internet Pharmacy" may not be legitimate and should not be used as a source for controlled substances are the following:

- The site is not a participant in any insurance plan and requires that all payments be made with a credit card.
- The site requires that you waive some rights before they send you the drugs.
- The site advises you about the law and why it is permissible for you to obtain pharmaceutical controlled substances from foreign countries via the Internet.
- The site does not ask the name, address, or phone number of your current physician.
- The site advises you to have the drugs sent to post office boxes or other locations to avoid detection by U.S. authorities.

I Have Seen a VIPPS Seal on Some Internet Pharmacy Sites. What Does This Mean?

The National Association of Boards of Pharmacy (NABP) has developed a voluntary program called the Verified Internet Pharmacy Practice Sites (VIPPS). The NABP has begun issuing a "seal of approval" to Internet pharmacies that meet standards regarding State licensing and DEA registration. To be VIPPS certified, a pharmacy must comply with the licensing and inspection requirements of their State and each State to which they dispense pharmaceuticals. In addition, pharmacies displaying the VIPPS seal have demonstrated to NABP compliance with VIPPS criteria including patient rights to privacy, authentication and security of prescription orders, adherence to a recognized quality assurance policy, and provision of meaningful consultation between patients and pharmacists. The NABP also provides information on whether a pharmacy is licensed and in good standing (see *http://www.nabp.net*).

Are the Rules Different for "Life Style" Drugs?

Some people have applied the phrase "life style drugs" to certain medications, such as Viagra, weight control medications, and tranquilizers. Many of the so-called life style drugs are not controlled substances. If a "life style" drug is a controlled substance, however, it is still subject to all regulations for controlled substances. You must obtain a prescription from a DEA registered prescriber and have it filled by a DEA registered pharmacy.

I Have a Complaint About an "Internet Pharmacy" Site on the Internet That Appears to be Illegally Selling Drugs. Where Should I Send the Complaint?

If the complaint involves a pharmaceutical controlled substance, contact the DEA, Office of Diversion Control, Drug Operations Section, Washington, DC 20537, telephone (202) 307–7194 or your local DEA office (for a list of contacts, see *http://www.dea.gov/agency/domestic.htm.*)

If the complaint involves any pharmaceutical drug other than a controlled substance, contact the U.S. Food and Drug Administration, HFC–230, 5600 Fishers Lane, Rockville, MD 20857, or file a report on the FDA's web site at *http://www.fda.gov/oc/buyonline/buyonlineform.htm.*

If the complaint involves a pharmacist or a physician, you may contact the State Board of Pharmacy or the State Board of Medicine where the doctor or pharmacist is located.

Additionally, you may wish to view other sites on the Internet that are for registering complaints such as the NABP (*http://www.nabp.net*).

Dated: March 19, 2001.

Laura M. Nagel,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. 01–10255 Filed 4–26–01; 8:45 am]

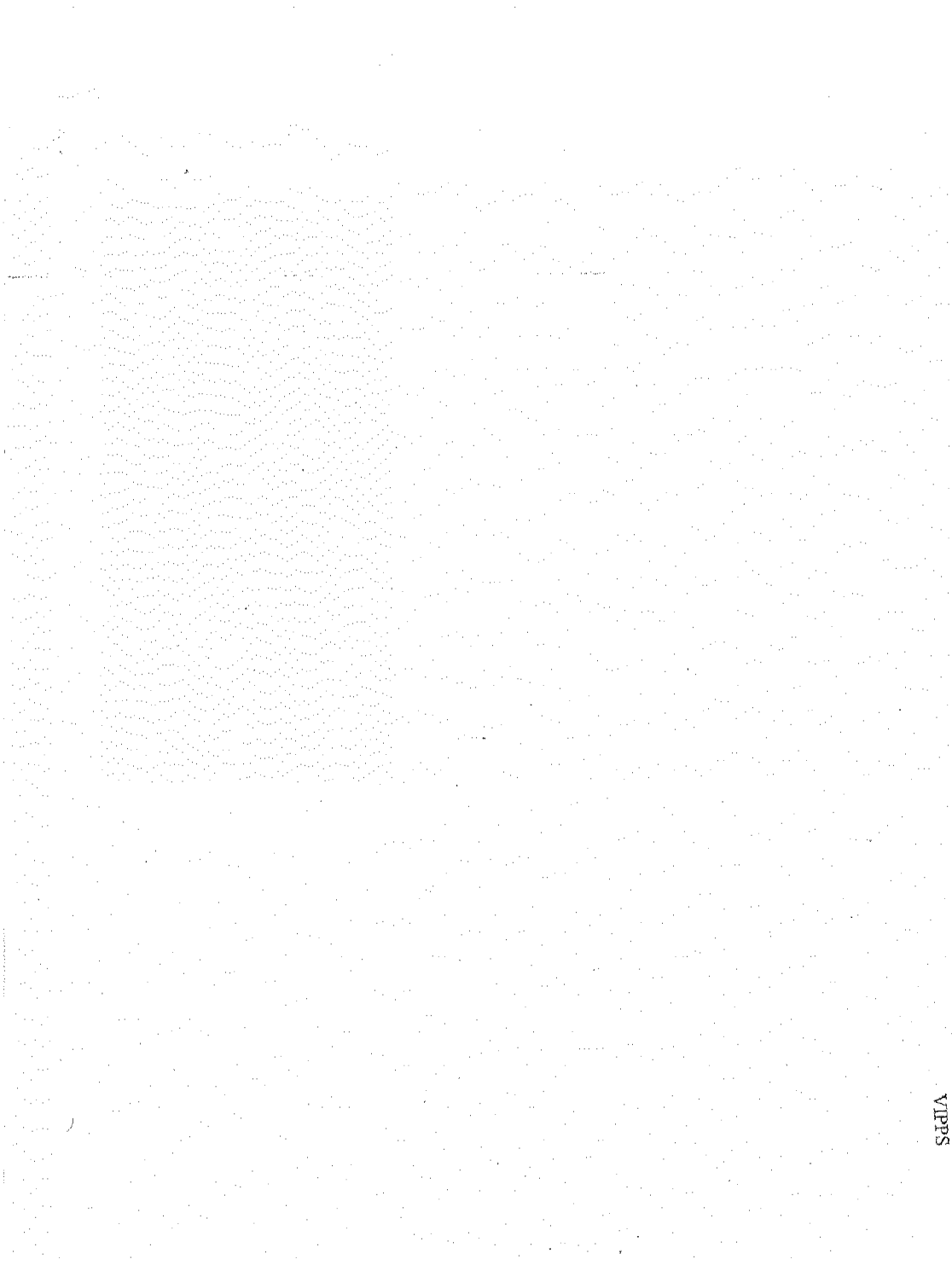
BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Employment Standards Administration Wage and Hour Division

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor are issued in accordance with applicable law and are based on the information obtained by the Department of Labor from its study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FDA

Verified Internet Pharmacy Practice Sites™ (VIPPS®)

Most Frequently Asked Questions

VIPPS® PROGRAM

What is the VIPPS Program?

The Verified Internet Pharmacy Practice Sites™ (VIPPS®) program and its accompanying VIPPS seal of approval identifies to the public those online pharmacy practice sites that are appropriately licensed, are legitimately operating via the Internet, and that have successfully completed a rigorous criteria review and inspection.

How does NABP verify the sites?

Internet-based pharmacy practice sites wishing to become VIPPS-certified submit a detailed application to NABP, which includes the pharmacy's policies and procedures addressing the VIPPS criteria. Licensure information is verified with applicable state boards of pharmacy. The VIPPS team reviews the application, policies, and applicant's Web site, and performs an on-site inspection of the pharmacy's facilities. Once the policies and procedures as well as the operations of the pharmacy appear to meet the intent of the VIPPS criteria, permission to display the VIPPS Seal is granted and the verified information about the pharmacy is posted on the VIPPS Web site. Clicking on the VIPPS Seal links the user to the VIPPS Web site that then verifies that the Seal is indeed posted on a VIPPS-certified site. If so, the user is then shown pharmacy-specific information, including licensure information.

Does NABP regulate online pharmacies?

NABP does not regulate online pharmacies. Regulation of pharmacy practice, whether online or not, is primarily the jurisdiction of the state boards of pharmacy with some federal oversight. The VIPPS program is a voluntary certification program for which Internet pharmacy practice sites may apply. The value of the program to the patient and the Internet pharmacy is that it provides members of the public with a means to assure themselves that the Internet pharmacy they choose is a bona fide, fully licensed facility exercising competent Internet/interstate pharmacy practices.

When was the VIPPS program developed?

In 1999, NABP became aware of the need for this program when consumers contacted several state pharmacy boards to complain about illegal Internet prescribing and dispensing sites posing as legitimate pharmacies. The Association developed the VIPPS program in response to public and regulatory agency concerns regarding safety of Internet pharmacy practices in order to provide a means for the public to distinguish between legitimate and illegitimate online pharmacy practice sites.

Isn't the number of Internet sites far too large to monitor and control?

No. NABP and the regulatory framework of state boards of pharmacy, federal agencies, and the medical community have been working together for several years now to achieve this goal.

Online Pharmacy Questions

How many online pharmacies are out there?

It is difficult, if not impossible, to answer this question accurately, but it is probably fewer than you would think. Illegitimate pharmacies (usually those that offer online prescribing) open and close on a daily basis. One company posing as a legitimate pharmacy may have many URLs or Web addresses, creating the impression that there is a greater number of Internet pharmacies than actually exists. In addition, pharmacies may only register with select search engines. If these search engines are not utilized when performing a search then all pharmacies may not be counted.

How many prescribing sites are out there?

The number of prescribing sites, using patient questionnaires and fee-based

cyberspace consultations, as well as sites that sell prescription medications and controlled substances without requiring a "consult," is difficult to estimate. NABP's research indicates that the number of such rogue operators is less than the number of legitimate online dispensing pharmacies.

What's wrong with using a prescribing site to get Viagra® and Xenical®? I don't have to see a doctor and can obtain the medicine with increased privacy and confidentiality; and it's cheaper.

First, the Food and Drug Administration (FDA) restricts the distribution of certain drugs to a prescription-only basis because in certain medical situations they can be dangerous if not taken with ongoing medical consultation. Most regulatory authorities and professional organizations regard online prescribing to be unprofessional, and in some states it is illegal, unless it is done pursuant to a valid, ongoing patient-prescriber relationship that has included an in-person physical examination. Completing only an online questionnaire does not establish a valid patient-prescriber relationship. Moreover, without a physical examination you could receive inappropriate medication and worsen an underlying, undiagnosed, serious medical condition.

As for increased privacy and confidentiality, evidence appears to indicate that illegitimate prescribing sites frequently sell their customer lists to other illegitimate online pharmacy operators and owners of Internet scam and pornography sites. By buying drugs from an illegitimate site you may be designating yourself as someone who is a good target for rip-off schemes.

Frequently, deceived consumers notify us of non-receipt of medications they ordered, and/or credit card charges that illegitimately operating pharmacies refuse to remove. Many also complain that they are unable to contact the pharmacies: phone lines are disconnected or no one answers.

Can I get really cheap prices from pharmacies outside the US?

First, the FDA generally prohibits the importation of foreign-made versions of prescription medications that are commercially available in the US. The safety and efficacy of these medications cannot be guaranteed. Many countries' drug research and control programs are not as safety oriented as those in the US. Though some of the drugs advertised by foreign sites may be manufactured by the same name brand international drug manufacturer as you are used to, they usually are not manufactured in FDA inspected facilities that have met FDA standards. Further, sometimes the

medications have been subjected to storage conditions that compromised their potency or safety.

Can I get cheap prices from legitimate online pharmacies?

Yes, and more. One of the great benefits to shopping online to fill your prescriptions is the ease with which you can comparison shop. Many pharmacies offer price comparisons between their charge and that of other legitimate pharmacies. This is one way to stretch your health care dollar. Many online pharmacies accept prescription benefit insurance coverage as well. In addition, legitimate online pharmacies often offer valuable health care information in a searchable format. VIPPS-certified pharmacies are required to offer their customers free phone consultation with a pharmacist, and many offer free ask-a-pharmacist e-mail service as well.

What are the main advantages of ordering medications online?

Convenience is a major advantage that online pharmacies provide over some of their pharmacy competitors. Consumers' ability to order and receive medications without leaving their home is a tremendous time-saver. Often, drug information and price information may be accessed via the pharmacy's Web site, or this information may be requested via e-mail so the consumer does not have to wait on the phone for an answer or travel to the pharmacy to ask for this information in person.

In addition, online pharmacies may provide more privacy than traditional brick-and-mortar pharmacies. Consumers who are too embarrassed to purchase certain medications or health care products from the local pharmacy may find greater anonymity by ordering these products from an e-pharmacy where staff may not be able to put a "face to a name."

Laws/Regulations

Who regulates online pharmacies?

The state boards of pharmacy have primary responsibility for regulation of online pharmacies. Regulatory authority is mainly exercised by the state board of pharmacy of the state in which the pharmacy is physically located. In addition, most states protect their citizens by licensing "out-of-state pharmacies" that ship medications to patients in their jurisdictions. The same regulations that apply to traditional brick-and-mortar and mail-order pharmacies typically apply to online pharmacies. Federal agencies, such as

the FDA and Drug Enforcement Administration (DEA), are also partners with the state boards of pharmacy in this regulatory process. The FDA, however, mainly regulates foreign-based sites and practitioners.

How do I set-up an online pharmacy?

When pharmacists are thinking about setting up an online pharmacy, we encourage them to do their homework and work in conjunction with the state boards of pharmacy. The VIPPS criteria may serve as a solid guideline when an organization plans to expand into interstate/Internet pharmacy practice and seeks to address issues of quality, verifiable relationships, regulatory compliance, and good pharmacy practices.

How does NABP work with government agencies that regulate online pharmacies?

NABP has strong working relationships with the state boards of pharmacy and the federal agencies. Inspector training programs and the VIPPS "Report a Suspicious Site" programs are examples of ways in which NABP helps regulatory agencies monitor and investigate illegitimate pharmacy Web sites.

How are international online sites regulated?

As mentioned earlier, online sites located outside the United States pose the greatest challenges for state and federal regulators. Cooperation with other nations and their regulatory agencies has been and continues to be the key to regulating online international pharmacy sites. NABP is working with a number of international regulatory agencies to establish VIPPS programs for their online pharmacies.

What organization can I contact regarding regulations and online pharmacies?

Your first contact should be the local state board of pharmacy . You may also subscribe to NABPLAW®, NABP's state pharmacy law and rules database, which allows users to research subjects one state at a time or across all 50 states. Annual subscriptions include two updates to assure users' access to the most accurate information possible. For more information contact NABP's Publications Desk, or e-mail NABP at custserv@nabp.net.

What if I believe an online pharmacy has dispensed the wrong medication or labeled the medication incorrectly?

Please report these incidents to your local state board of pharmacy as well as the board of pharmacy in the state where the pharmacy is located. You should also contact the pharmacy that mistakenly dispensed the medication. VIPPS pharmacies are required to document, track, and analyze these types of incidents to determine what went wrong and to prevent recurrences.

What are the signs of a suspiciously operating pharmacy?

First, e-pharmacies are suspect if they dispense prescription medications without requiring the consumer to mail in a prescription, and if they dispense prescription medications and do not contact the patient's prescriber to obtain a valid verbal prescription. Further, online pharmacies are suspect if they dispense prescription medications solely based upon the consumer completing an online questionnaire without the consumer having a pre-existing relationship with a prescriber and the benefit of an in-person physical examination. State boards of pharmacy, boards of medicine, the FDA, as well as the AMA, condemn this practice and consider it to be unprofessional.

Second, online pharmacies should have a toll-free phone number as well as a street address posted on their site. If the pharmacy merely has an e-mail feature, so that the sole means of communication between the consumer and the pharmacy is via e-mail, this is a suspect site.

Third, legitimate sites allow consumers to contact pharmacists if they have questions about their medications. If a site does not advertise the availability of pharmacists for medication consultation, it should be avoided.

Many suspiciously operating e-pharmacies have limited numbers of medications that they sell, particularly "lifestyle" medications that treat such conditions and diseases as impotence, obesity, herpes, pain, and acne. Although pharmacies may not sell every medication available in the US, those online pharmacies solely selling lifestyle medications may not be operating legitimately.

What if I believe that an online pharmacy may be operating suspiciously?

Please report suspiciously operating pharmacies to NABP by using the "Report-a-Site" feature in the VIPPS section of our Web site. You may do so anonymously. We also encourage you to report such sites to your local state board of pharmacy, especially if

you or a loved one has been harmed. NABP forwards information regarding suspiciously operating sites to the most appropriate regulatory authorities.

What organization covers the security of patient information for online pharmacies?

Security, confidentiality, and privacy are among the chief concerns of patients and health care professionals regarding online pharmacy services. State and federal laws such as the Health Insurance Portability and Accountability Act (HIPAA) protect patient identifiable information. VIPPS and other voluntary certification programs require participating organizations to adhere to and post their privacy policies. In addition, NABP has published guidelines regarding the confidentiality of patient health care information. Please contact NABP, 847/391-4406, for information about obtaining a copy of these guidelines.

Prescriptions/Prescribers

Can a prescription be faxed to the online pharmacy, or does the pharmacy need the original prescription? Does the online pharmacy verify the prescription with the prescriber?

Generally state laws require faxed prescriptions to be received directly from the prescriber (not the patient) to be valid. Online sites that do not protect the integrity of the original prescription, or that do not verify the authenticity of suspect prescriptions may be in violation of the law. In addition, VIPPS-certified pharmacies must have policies and procedures in place that address these issues. Before you entrust your health to anyone online, look for the VIPPS Seal, and click to verify.

Disclaimer

Last modified: 12-31-01

requently Asked Questions - Verified Internet Pharmacy Practice Sites

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FDA

VIPPS® Certification Process

The VIPPS certification process begins when the applicant submits a VIPPS application form with application fee Application form and Instructions)

- Upon receipt of the application form and supporting documentation, NABP staff will:
  - Verify all necessary state pharmacy licenses are in good standing
  - Verify the Pharmacist-in-Charge licenses are in good standing
  - Evaluate the submitted support documents against the Interpretive Guide to the VIPPS Criteria
- Notify the applicant if discrepancies arise or clarification is needed.
- After review of the documentation, staff schedules an on-site inspection of the pharmacy to evaluate the policies and staff for compliance with the VIPPS criteria.
  Inspections may be required:
  - Upon notice of a complaint against a VIPPS certified pharmacy
  - At the request of a participant in the course of VIPPS certification suspension action.
  - Re-inspections of VIPPS-Certified pharmacies are required once every three years.
- Following review of the application materials, verification of submitted information and licensure, and insp be sent to the pharmacy. If the review is satisfactory the report will include:
  - a VIPPS Letter of Agreement to be signed by an authorized representative or agent of the entity w entity
  - an invoice for the first year participation fee.
- Upon receipt of the executed Letter of Agreement and fee, NABP releases a code to the applicant which area of the VIPPS Web site where the applicant may retrieve and download their VIPPS hyperlink Seal a administrative functions. Guidelines for the use of the Seal are included in the Letter of Agreement.
- The VIPPS certification is renewable annually following an update of the registration information and re-v status.

The entire process from initial application to award of the Seal should take one to two months depending on sche quality of the applicant's response.

VIPPS Certified Pharmacies receive:

- NABP/VIPPS hyperlink Seal to display on their Web site. Focus group studies have demonstrated the Se to prospective Internet pharmacy users for a number of reasons.
  - To those trusting their health and life to an unknown entity on the Internet, the NABP Seal represe a hundred-year heritage of dedication to protecting the public health through assisting state board pharmacy practices.
  - The public can access comprehensive company information regarding each VIPPS pharmacy.
  - Patients appreciate the clear, understandable, and professionally reviewed requirements, which a merit of certification for themselves.
  - The certification requirements address their fears and concerns.
- Expanded Internet presence. NABP is committed to supply a network of connections from its Web site to NABP is also working to establish referral links to its Web site from not-for-profit organizations and other sites. Once in the VIPPS site, visitors may search the database for the Internet pharmacy of their choice.
- A comprehensive overview of their pharmacy operations and policies, with suggestions for improvements services.
- VIPPS Pharmacies also may find benefit from access to NABP resources and expertise in licensure, prof regulatory compliance.

Disclaimer

Last Modified: October 14, 2005

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VIPPS Database Search Results

Your search yielded 12 pharmacy(s):

Detail	Web Business Name	Website Address
	Anthem Prescription	www.anthemprescription.com
	Caremark.com	www.caremark.com
	DrugSource, Inc.	www.drugsourceinc.com
	drugstore.com	www.drugstore.com
	Familymeds.com	www.Familymeds.com
	HOOK SUPERX, Inc, dba CVS/pharmacy	www.cvs.com
	Medco Health Solutions, Inc.	www.medcohealth.com
	Omnicare, Inc dba Care for Life	www.careforlife.com
	Prescription Solutions	www.rxsolutions.com
	RxWEST Pharmacy	www.rxwest.com
	Tel-Drug, Inc./CIGNA	www.teldrug.com
	Walgreens, Co.	www.walgreens.com

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AMA

H-120.949 Guidance for Physicians on Internet Prescribing

Our AMA provides the following guidance for physicians on the appropriate use of the Internet in prescribing medications:

(a) Criteria for an acceptable patient (clinical) encounter and follow-up: Physicians who prescribe medications via the Internet shall establish, or have established, a valid patient-physician relationship, including, but not limited to, the following components. The physician shall: (i) obtain a reliable medical history and perform a physical examination of the patient, adequate to establish the diagnosis for which the drug is being prescribed and to identify underlying conditions and/or contraindications to the treatment recommended/provided; (ii)have sufficient dialogue with the patient regarding treatment options and the risks and benefits of treatment(s); (iii) as appropriate, follow up with the patient to assess the therapeutic outcome; (iv) maintain a contemporaneous medical record that is readily available to the patient and, subject to the patient's consent, to his or her other health care professionals; and (v) include the electronic prescription information as part of the patient medical record. Exceptions to the above criteria exist in the following specific instances: treatment provided in consultation with another physician who has an ongoing professional relationship with the patient, and who has agreed to supervise the patient's treatment, including use of any prescribed medications; and on-call or cross-coverage situations.

(b) Licensure Physicians who prescribe medications via the Internet across state lines, without physically being located in the state(s) where the patient (clinical) encounter(s) occurs, must possess appropriate licensure in all jurisdictions where patients reside. An exception to this requirement is when the clinical encounter with the patient, as described in recommendation 1(a) above, occurs in the state where the physician is licensed and his or her practice is located, and the state where the patient resides allows electronic prescriptions from out-of-state prescribers.

(c) Security of patient information Physicians who prescribe via the Internet should transmit prescriptions over a secure network (i.e., provisions for password protection, encrypted electronic prescriptions, or other reliable authentication techniques [e.g., AMA Internet ID]) in order to protect patient privacy.

(d) Disclosure of identifying information on web sites Physicians who practice medicine via the Internet, including prescribing, should clearly disclose physician-identifying information on the web site, including (but not necessarily limited to) name, practice location (address and contact information), and all states in which

licensure is held. Posting of actual physicians' license numbers (e.g., the DEA number) is unnecessary.

(e) Liability exposure Physicians should be aware that they may increase their liability exposure by prescribing medications to individuals solely through online interactions (e.g., online questionnaire or online consultation). (BOT Rep. 7, A-03; Reaffirmed: BOT Rep. 3, I-04; Reaffirmed: Sub. Res. 522, A-05)

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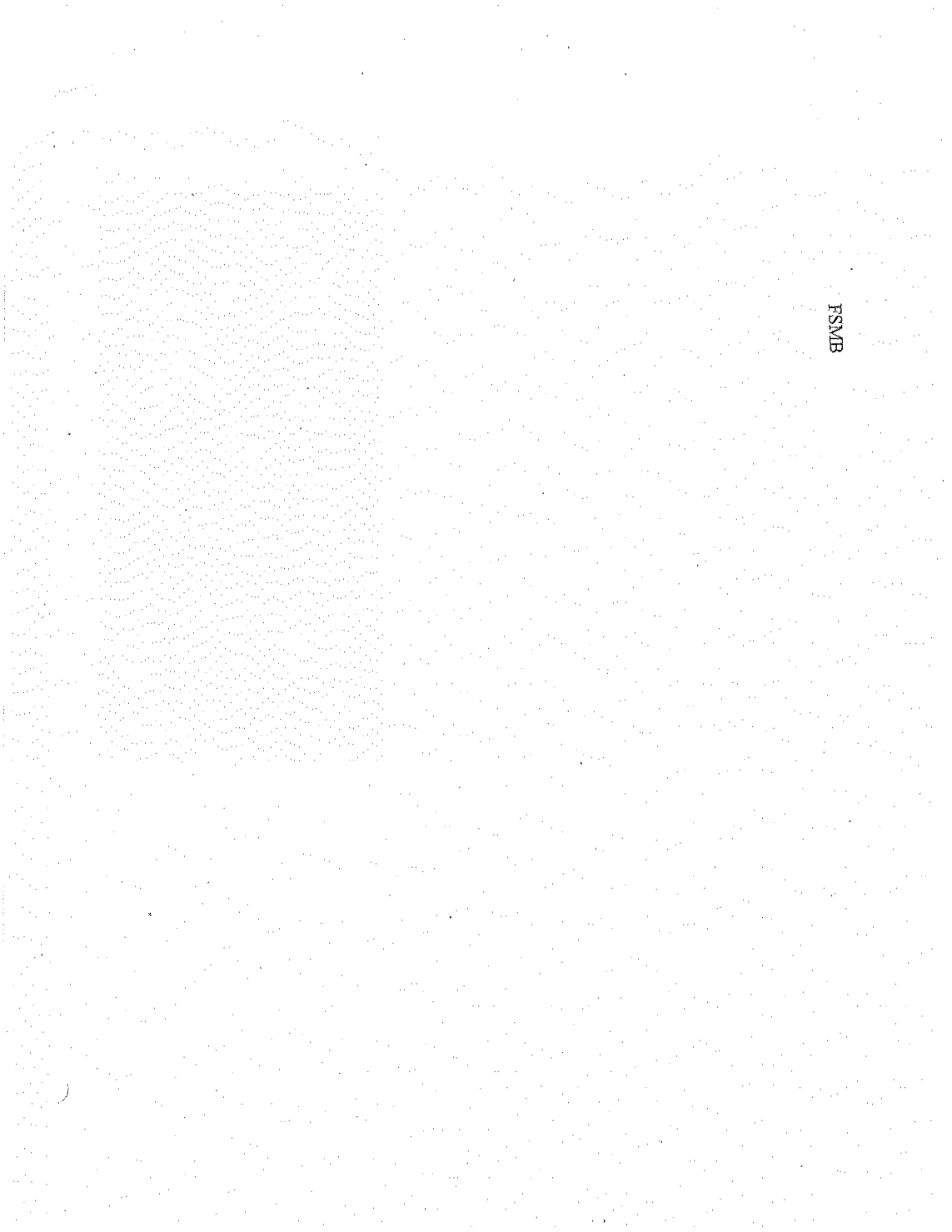
FSMB

Report of the Special Committee on Professional Conduct and Ethics

Federation of State Medical Boards of the United States, Inc.

The recommendations contained herein were adopted as policy by the House of Delegates of the Federation of State medical Boards of the United States, Inc., April 2002

Introduction

In April 2000, the Federation's House of Delegates adopted 15 recommendations issued by the Special Committee on Professional Conduct and Ethics focusing on physician behaviors and practices which negatively impact (1) patient safety and welfare, and/or (2) the physician-patient relationship. The recommendations pertain to physician activities in five specific areas:

- Disruptive behavior by physicians
- The sale of goods from physician offices
- Boundary issues and patient surrogates
- Participation in business or contractual relationships
- Regulation of Internet prescribing

Recommendation Nine of the Special Committee's Report called for the Federation of State Medical Boards to study the practice of medicine via the Internet as to the impact on public health and safety and develop guidelines for state medical boards to use in educating licensees as to the appropriate use of the Internet in medical practice. Then Federation President George C. Barrett, MD, extended the charge of the Special Committee on Professional Conduct and Ethics to fulfill the adopted recommendation.

In developing the guidelines that follow, the Committee evaluated current and projected use of the Internet in the delivery of health care services and identified two distinct areas of e-health: health information and delivery of patient care. The Committee focused the guidelines on the latter due to its direct impact on patient safety and welfare and the physician-patient relationship.

The recommendations contained herein were adopted as policy by the House of Delegates of the Federation of State medical Boards of the United States, Inc., April 2002

Model Guidelines for the Appropriate use of the Internet in Medical Practice

Section I. Preamble

The Internet has had a profound impact on the practice of medicine and offers opportunities for improving the delivery and accessibility of health care. Studies show a growing number of physicians are utilizing the Internet to some degree in their practices and patients want to receive certain medical services online[1]. However, patient safety concerns, especially as related to providing medical services via the Internet, including prescribing and dispensing medications, have created complex regulatory challenges for state medical boards in protecting the public.

The (*name of board*) recognizes that the Internet offers potential benefits in the provision of medical care. The appropriate application of this technology can enhance medical care by facilitating communication with physicians and other health care

providers, refilling prescriptions, obtaining laboratory results, scheduling appointments, monitoring chronic conditions, providing health care information and clarifying medical advice. However, it is the expectation of the Board that e-mail and other electronic communications and interactions between the physician and patient should supplement and enhance, but not replace, crucial interpersonal interactions that create the very basis of the physician-patient relationship.

The Board has developed these guidelines to educate licensees as to the appropriate use of the Internet in medical practice. The *(name of board)* is committed to assuring patient access to the convenience and benefits afforded by the Internet while promoting the responsible practice of medicine by physicians.

It is the expectation of the Board that physicians who provide medical care, electronically or otherwise, maintain a high degree of professionalism and should:

- Place the welfare of patients first
- Maintain acceptable standards of practice
- Adhere to recognized ethical codes governing the medical profession
- Properly supervise physician extenders
- Protect patient confidentiality

Section II. Parity of Professional and Ethical Standards

There should be parity of ethical and professional standards applied to all aspects of a physician's practice. Related to the use of the Internet in a physician's practice, the Board expects the following ethical standards to be observed:

Candor:
Physicians have an obligation to disclose clearly information (financial, professional, or personal) that could influence patients' understanding or use of the information, products or services offered on any Web site offering health care services or information.

Privacy:
Physicians have an obligation to prevent unauthorized access to or use of patient and personal data and to assure that "de-identified" data cannot be linked back to the user or patient.

Integrity:
Information contained on Web sites should be truthful and not misleading or deceptive. It should be accurate and concise, up to date, and easy for patients to understand. Physicians associated with medical Web sites should strive to ensure that information provided be supported by current medical peer review literature, emanates from a recognized body of knowledge, and conforms to minimal standards of care. It should clearly indicate whether it is based upon scientific studies, expert consensus, professional experience or personal opinion.

Informed Consent:
Delivery of medical services via the Internet requires expanded responsibility on the part of the physician in informing and educating the patient. A patient has the right to know what personal data may be gathered and by whom. The physician must obtain material and informed consent from the patient to collect, share or use personal data. It should be clearly explained to patients when online communication should not take the place of a face-to-face interaction with a health care provider.

Accountability:
Physicians have an obligation to provide meaningful opportunities for patients to give feedback about their concerns and to review and respond to those concerns in a timely and appropriate manner.

Section III. An Appropriate Physician-Patient Relationship

The health and well-being of patients depends upon a collaborative effort between physician and patient.[2] The relationship between physician and patient is complex and is based on the mutual understanding between physician and patient of the shared responsibility for the patient's health care. Although the Board recognizes that it may be difficult in some circumstances, particularly in an online setting, to define precisely the beginning of the physician-patient relationship, it tends

to begin when an individual seeks assistance from a physician with a health-related matter for which the physician may provide assistance. However, the relationship is clearly established when the physician agrees to undertake diagnosis and treatment of the patient and the patient agrees, whether or not there has been a personal encounter between the physician (or other supervised health care practitioner) and patient.

The physician-patient relationship is fundamental to the provision of acceptable medical care. It is the expectation of the Board that physicians recognize the obligations, responsibilities and patient rights associated with establishing and maintaining an appropriate physician-patient relationship whether or not interpersonal contact between physician and patient has occurred.

Section IV. Definitions

For the purpose of these guidelines, the following definitions apply:

"Medical Practice Site" means a patient-specific Internet site, access to which is limited to licensed physicians, associated medical personnel and patients. It is an interactive site and thus qualifies as a practice location. It requires a defined physician-patient relationship.

"General Health Information Site" means a non-interactive Internet site that is accessible by anyone with access to the Internet and intended to provide general, user non-specific information or advice about maintaining health or the treatment of an acute or chronic illness, health condition or disease state.

"Personal Health Information" means any personally-identifiable information, whether oral or recorded in any form or medium, that is created or received by a physician or other health care provider and relates to the past, present or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual.[3]

"Physician-patient e-mail" means computer-based communication between physicians (or their medical personnel) and patients within a professional relationship in which the physician has taken on an explicit measure of responsibility for the patient's care.[4]

"Passive tracking mechanism" means a persistent electronic file used to track Web site navigation, which allows the Web site to record, and retain user-specific navigation information whenever the user accesses the Web site. Examples include "cookies," "clear gifts" or "Web bugs."[5]

"Web site" means an electronic source of health information content, commerce, connectivity and/or service delivery.[6]

Section V. Guidelines for the Appropriate Use of the Internet in Medical Practice

The Board has adopted the following guidelines for physicians utilizing the Internet in the delivery of patient care:

Evaluation of the Patient
A documented patient evaluation, including history and physical evaluation adequate to establish diagnoses and identify underlying conditions and/or contra-indications to the treatment recommended/provided, must be obtained prior to providing treatment, including issuing prescriptions, electronically or otherwise.

Treatment
Treatment and consultation recommendations made in an online setting, including issuing a prescription via electronic means, will be held to the same standards of appropriate practice as those in traditional (face-to-face) settings. Treatment, including issuing a prescription, based solely on an online questionnaire or consultation does not constitute an acceptable standard of care.

Electronic Communications
Written policies and procedures should be maintained for the use of patient-physician electronic mail. Such policies and procedures should address (1) privacy, (2) health care personnel (in addition to the physician addressee), who will process messages, (3) hours of operation, (4) types of transactions that will be permitted electronically, (5) required patient information to be included in the communication, such as patient name, identification number and type of transaction, (6) archival and retrieval, and (7) quality oversight mechanisms. Policies and procedures should be periodically evaluated for currency and be maintained in an accessible and readily available manner for review.

Sufficient security measures must be in place and documented to assure confidentiality and integrity of patient-identifiable information. Transmissions, including patient e-mail, prescriptions, and laboratory results must be secure within existing technology (i.e., password protected, encrypted electronic prescriptions, or other reliable authentication techniques). All patient-physician e-mail, as well as other patient-related electronic communications, should be stored and filed in the patient's medical record.

Turnaround time should be established for patient-physician e-mail and medical practice sites should clearly indicate alternative form(s) of communication for urgent matters. E-mail systems should be configured to include an automatic reply to acknowledge message delivery and that messages have been read. Patients should be encouraged to confirm that they have received and read messages.

Informed Consent
A written agreement should be employed documenting patient informed consent for the use of patient-physician e-mail. The agreement should be discussed with and signed by the patient and included in the medical record. The agreement should include the following terms:

- Types of transmissions that will be permitted (prescription refills, appointment scheduling, patient education, etc.)
- Under what circumstances alternate forms of communication or office visits should be utilized
- Security measures, such as encrypting data, password protected screen savers and data files, or utilizing other reliable authentication techniques, as well as potential risks to privacy
- Hold harmless clause for information lost due to technical failures
- Requirement for express patient consent to forward patient-identifiable information to a third party
- Patient's failure to comply with the agreement may result in physician terminating the e-mail relationship

Medical Records
The medical record should include copies of all patient-related electronic communications, including patient-physician e-mail, prescriptions, laboratory and test results, evaluations and consultations, records of past care and instructions. Informed consent agreements related to the use of e-mail should also be filed in the medical record.

Patient medical records should remain current and accessible for review and be maintained in compliance with applicable state and federal requirements.

Compliance with State and Federal Laws and Web Standards
Physicians should meet or exceed applicable federal and state legal requirements of medical/health information privacy. Physicians are referred to "Standards for Privacy of Individually Identifiable Health Information" issued by the Department of Health and Human Services (HHS).[7] Guidance documents are available on the HHS Office for Civil Rights Web site at www.hhs.gov/ocr/hipaa.

Physicians who treat or prescribe through Internet Web sites are practicing medicine and must possess appropriate licensure in all jurisdictions where patients reside.[8]

Physicians are encouraged to comply with nationally recognized health Web site standards and codes of ethics, such as those promulgated by the American Medical Association, Health Ethics Initiative 2000, Health on the Net and the American Accreditation HealthCare Commission (URAC).

Disclosure
Physician medical practice sites should clearly disclose:

- Owner of the site
- Specific services provided
- Office address and contact information

- Licensure and qualifications of physician(s) and associated health care providers
- Fees for online consultation and services and how payment is to be made
- Financial interests in any information, products or services
- Appropriate uses and limitations of the site, including providing health advice and emergency health situations
- Uses and response times for e-mails, electronic messages and other communications transmitted via the site
- To whom patient health information may be disclosed and for what purpose
- Rights of patients with respect to patient health information
- Information collected and any passive tracking mechanisms utilized

Accountability
Medical practice sites should provide patients a clear mechanism to:

- access, supplement and amend patient-provided personal health information
- provide feedback regarding the site and the quality of information and services
- register complaints, including information regarding filing a complaint with the applicable state medical board(s)

Advertising/Promotion of Goods or Products
Advertising or promotion of goods or products from which the physician receives direct remuneration, benefits or incentives is prohibited.

Links
Physician Web sites may provide links to general health information sites to enhance patient education; however, the physician should not benefit financially from providing such links or from the services or products marketed by such links. When providing links to other sites, physicians should be aware of the implied endorsement of the information, services or products offered from such sites.

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[1] AMA. Report of the Council on Medical Service, Medical Care Online.

[2] AMA, Council on Ethical and Judicial Affairs, Fundamental Elements of the Patient-Physician Relationship.

[3] Health Web Site Standards, Version 1.0, 2001 URAC

[4] Policy H-478.997, American Medical Association

[5] Health Web Site Standards, Version 1.0, 2001 URAC

[6] Health Web Site Standards, Verson 1.0, 2001 URAC

[7] Federal Register, December 28, 2000.

[8] FSMB. A Model Act to Regulate the Practice of Medicine Across State Lines, (HOD 1996).

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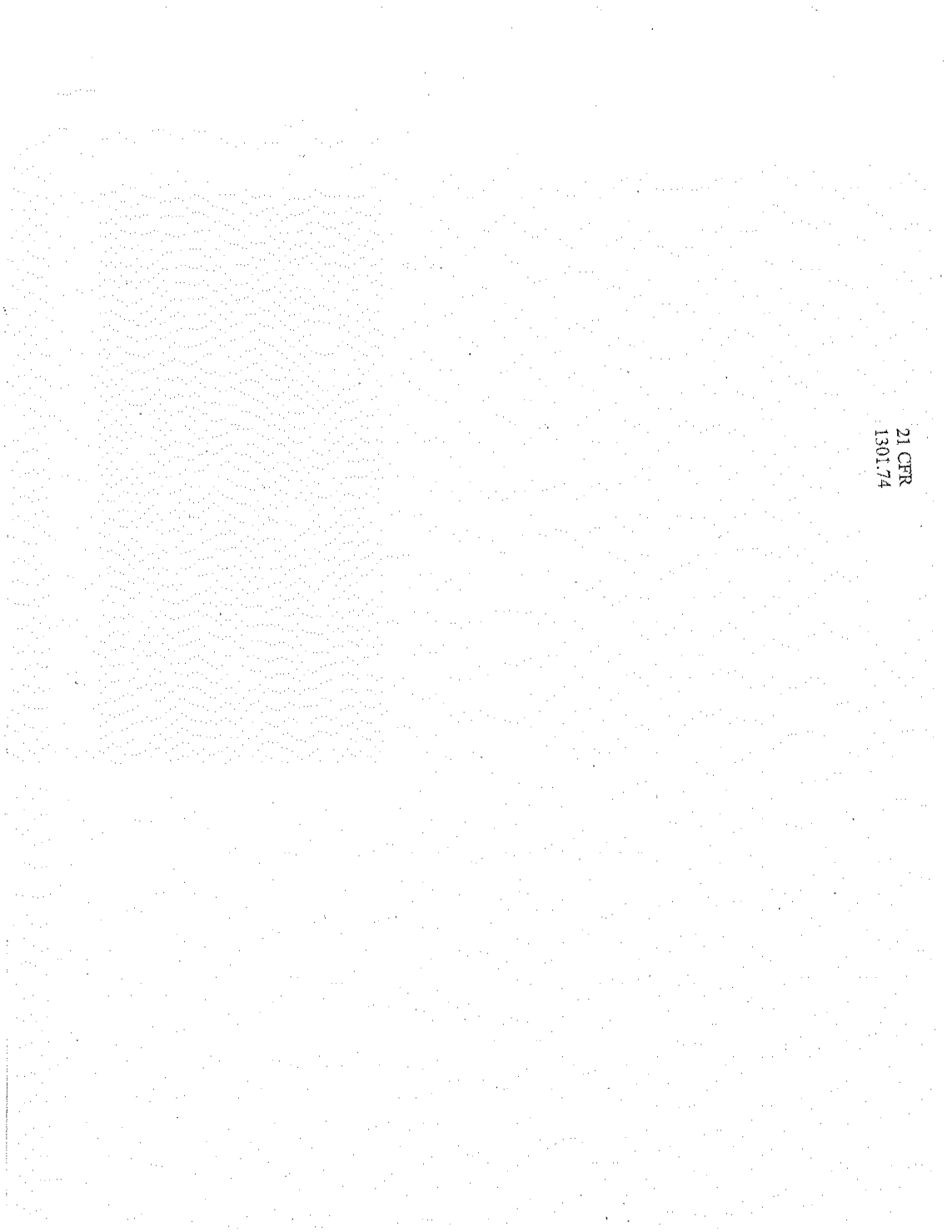

21 CFR
1301.74

f Federal Regulations]
[Title 21, Volume 9]
[Revised as of April 1, 2005]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR1301.74]

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TITLE 21-FOOD AND DRUGS

CHAPTER II--DRUG ENFORCEMENT ADMINISTRATION, DEPARTMENT OF JUSTICE

PART 1301 REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES--Table of Contents

Sec. 1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.

(a) Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Administration or with the appropriate State controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance.

(b) The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

(c) The registrant shall notify the Field Division Office of the Administration in his area of any theft or significant loss of any controlled substances upon discovery of such theft or loss. The supplier shall be responsible for reporting in-transit losses of controlled substances by the common or contract carrier selected pursuant to Sec. 1301.74(e), upon discovery of such theft or loss. The registrant shall also complete DEA Form 106 regarding such theft or loss. Thefts must be reported whether or not the controlled substances are subsequently recovered and/or the responsible parties are identified and action taken against them.

(d) The registrant shall not distribute any controlled substance listed in Schedules II through V as a complimentary sample to any potential or current customer (1) without the prior written request of the customer, (2) to be used only for satisfying the legitimate medical needs of patients of the customer, and (3) only in reasonable quantities. Such request must contain the name, address, and registration number of the customer and the name and quantity of the specific controlled substance desired. The request shall be preserved by the registrant with other records of distribution of controlled substances. In addition, the requirements of part 1305 of the chapter shall be complied with for any distribution of a controlled substance listed in Schedule II. For purposes of this paragraph, the term ``customer'' includes a person to whom a complimentary sample of a substance is given in order to encourage the prescribing or recommending of the substance by the person.

(e) When shipping controlled substances, a registrant is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses. When

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storing controlled substances in a public warehouse, a registrant is responsible for selecting a warehouseman which will provide adequate

security to guard against storage losses; wherever possible, the registrant shall store controlled substances in a public warehouse which complies with the requirements set forth in Sec. 1301.72. In addition, the registrant shall employ precautions (e.g., assuring that shipping containers do not indicate that contents are controlled substances) to guard against storage or in-transit losses.

(f) When distributing controlled substances through agents (e.g., detailmen), a registrant is responsible for providing and requiring adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.

(g) Before the initial distribution of carfentanil etorphine hydrochloride and/or diprenorphine to any person, the registrant must verify that the person is authorized to handle the substances(s) by contacting the Drug Enforcement Administration.

(h) The acceptance of delivery of narcotic substances by a narcotic treatment program shall be made only by a licensed practitioner employed at the facility or other authorized individuals designated in writing. At the time of delivery, the licensed practitioner or other authorized individual designated in writing (excluding persons currently or previously dependent on narcotic drugs), shall sign for the narcotics and place his specific title (if any) on any invoice. Copies of these signed invoices shall be kept by the distributor.

(i) Narcotics dispensed or administered at a narcotic treatment program will be dispensed or administered directly to the patient by either (1) the licensed practitioner, (2) a registered nurse under the direction of the licensed practitioner, (3) a licensed practical nurse under the direction of the licensed practitioner, or (4) a pharmacist under the direction of the licensed practitioner.

(j) Persons enrolled in a narcotic treatment program will be required to wait in an area physically separated from the narcotic storage and dispensing area. This requirement will be enforced by the program physician and employees.

(k) All narcotic treatment programs must comply with standards established by the Secretary of Health and Human Services (after consultation with the Administration) respecting the quantities of narcotic drugs which may be provided to persons enrolled in a narcotic treatment program for unsupervised use.

(l) DEA may exercise discretion regarding the degree of security required in narcotic treatment programs based on such factors as the location of a program, the number of patients enrolled in a program and the number of physicians, staff members and security guards. Similarly, such factors will be taken into consideration when evaluating existing security or requiring new security at a narcotic treatment program.

[36 FR 7778, Apr. 24, 1971; 36 FR 13386, July 21, 1971, as amended at 36 FR 18731, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

Editorial Note: For Federal Register citations affecting Sec. 1301.74, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

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Decision Questions

INTERNET PHARMACY
Decision Questions

1. Have you physically inspected the pharmacy? _____

2. Does the pharmacy accept walk-in customers? _____

3. Is the pharmacy licensed for sales in all required states? _____

4. Does the pharmacy purchase a wide range of drug products from distributors? _____

5. What percentage of the pharmacy's drug purchases are controlled substances? _____

6. Has the pharmacy requested to pick up orders rather than have them delivered to the pharmacy? _____

7. Is the pharmacy ordering more than 3,000 dosage units of phentermine a month? _____

8. Is the pharmacy ordering more than 5,000 dosage units of hydrocodone combination products a month? _____

9. Is the pharmacy ordering more than 5,000 dosage units of alprazolam a month? _____

10. If the pharmacy has a web site or is related to a web site:

    a. Are reasonable retail prices listed on the web site? _____

    b. Is there a patient medical history questionnaire on the web site? _____

    c. Does the prescribing doctor perform a physical exam of each patient? _____

    d. Does the website accept third party payment (i.e. insurance) for the Internet prescriptions? _____

    e. Does the web site offer to sell drugs without a prescription? _____

11. Is the pharmacy VIPPS certified? _____

12. Who pays the distributor for the drugs, the pharmacy or a third party? _____

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